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BIOMEDICAL RESEARCH, TRAINING, AND MEDICAL LIBRARY ASSISTANCE AMENDMENTS OF 1982

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Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2311]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2311) to revise and extend programs relating to biomedical research, research training, medical library assistance, health information and promotion, and research ethics, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

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I. SUMMARY OF THE BILL

S. 2311 amends the Public Health Service Act (hereinafter referred to as the Act) as follows:

(1) Reauthorizes the National Cancer Institute, the National Heart, Lung and Blood Institute, and the Medical Library Assistance Act for three years, through fiscal year 1985. Authorization levels for fiscal

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year 1983 are set at 6 percent above fiscal year 1982; authorizations for fiscal year 1984 at 5.5 percent above fiscal year 1983; for fiscal year 1985 at 5 percent above fiscal year 1984 (authorizations).

(2) Amends the National Cancer Institute legislation as follows:

(a) Authorizes Cancer Research and Cancer Control programs to include support for research projects related to "continuing care of the cancer patient and the patient's family."

(b) Authorizes Cancer Control programs to conduct "developmental research" in addition to current programs.

(c) Highlights the International Cancer Research Data Bank and requests its continued maintenance and operation, focusing on dissemination of cancer research and treatment data.

(3) Increases the ceiling of direct costs from $35,000 to $50,000 on grants which may be approved by NCI and NHLBI without referral to the national advisory boards.

(4) Extends the grant cycle for Cancer Centers from three to five years.

(5) Establishes in statute a National Kidney and Urologic Diseases Advisory Board.

(6) Authorizes the Diabetes, Arthritis, Kidney and Urologic Diseases, and Digestive Diseases Advisory Boards through 1985.

(7) Eliminates references to the Surgeon General which have been obsolete since 1966.

(8) Repeals payback requirements for National Research Service Awards.

(9) Amends health information and health promotion activities authorized in Title XVII of the Act to reauthorize and provide greater focus to the Office of Disease Prevention and Health Promotion including the authority to support projects in physical fitness and sports medicine. Sports Medicine and Physical Fitness programs (Sections 1706, 1707, 1708, 1709, 1710) are repealed.

(10) Reauthorizes the President's Commission for the Study of Ethical Problems in Title XVIII of the Act for two years through 1984.

(11) Requires two annual reports from NIH:

(a) Activities undertaken to improve grant, contracting, accountability and peer review procedures at NIH.

(b) All activities relating to preventive medicine and health promotion, including number and type of personnel involved.

(12) Requires Directors of each NIH institute to notify their advisory boards of any investigation concerning any recipient of a grant or contract from NIH.

(13) Requires the Director of NIH, within one year, to establish procedures for the appeal of determinations made on proposals for grants and contracts for biomedical research under the Act.

(14) Establishes a President's Council for the Health Sciences for a two-year period to provide a report on long-term health research goals for the Nation, and coordination of government-wide health research.

(15) Authorizes nurse anesthetist training programs for fiscal years 1983 and 1984.

(16) Amends the Act and the Health Planning and Resources Development Amendments of 1979 (Public Law 92–270) regarding

deadlines and penalties for State health planing and development agencies.

(17) Extends for six months certain requirements for grants under the Community Services Block Grant Act.

(18) Includes some technical and minor substantive amendments to the Act clarifying intent or correcting errors in the provisions of the Omnibus Reconciliation Act of 1981.

II. BACKGROUND AND NEED FOR LEGISLATION

The Biomedical Research, Training, and Medical Library Assistance Amendments of 1982 revises and extends a number of programs under the Public Health Service Act (hereinafter referred to as the Act), as well as making amendments to other Acts. Renewed authorizations are provided for several programs whose present authority will expire at the end of fiscal year 1982.

History and Accomplishments of the National Institutes of Health

The National Institutes of Health have slowly evolved from the one-room Laboratory of Hygiene established in 1887 to one of the largest biomedical research complexes in the world. The 1930 Ransdell Act officially created the first National Institute of Health. There are now eleven Institutes of Health, conducting research both in their own laboratories and by means of extramural grants to non-profit research institutions. In addition, they provide grants for buildings and other facilities and for training research scientists. The research and investigations undertaken with NIH support span all the health problems that afflict Americans, as well as the basic biological sciences, with the purpose of improving the health and quality of life for all by developing better means of prevention, treatment, detection, diagnosis, and cure of disease.

The National Cancer Institute Act of 1937 established the second National Institute of Health. In 1971, the National Cancer Act greatly increased the authority of the National Cancer Institute (NCI) Director; began the National Cancer Program; established a three-member President's Cancer Board and a twenty-three member National Cancer Advisory Board; established cancer control programs with State and other health agencies; and provided for the collection, analysis and dissemination of all data useful in the diagnosis, prevention, and treatment of cancer.

The National Cancer Program, under the direction of NCI, has made great strides in improving methods of detection, diagnosis, prevention and treatment of cancer. Of the one million Americans diagnosed with some form of cancer in 1977, 58 percent can expect to be cured of the disease using available treatments. Improved diagnostic methods, such as identifying antigens or enzymes produced by the cancer, can now help identify a cancer while it is at an earlier, more curable stage. In the area of prevention, scientists have greatly elucidated the role of lifestyle factors (such as smoking), and chemicals in the workplace and the environment in the causation of cancer, work which has led to public education about cancer risk, factors and reg-

ulations to limit exposure to cancer-causing agents and thereby prevent untold numbers of new cases of cancer.

Still, cancer remains the disease most feared by Americans. An explosion of information on fundamental processes of the cell over the past ten years provides many new opportunities for exploring the mechanisms of cancer causation which hold great promise for discovering means of prevention and cure.

With the passage of the National Heart Act of 1948, the National Heart Institute was created. The National Heart, Blood Vessel, Lung, reflect the increasing importance of diseases of the entire cardiopulmonary system, and in 1976 the name was changed to the National and Blood Act of 1972 expanded the authority of the Institute to Heart, Lung and Blood Institute (NHLBI). A few of the diseases investigated by this Institute include hypertension, stroke, pediatric respiratory distress, and sickle cell anemia.

For over 50 years diseases of the heart and blood vessels have been responsible for the greatest number of deaths in the United States. In 1978, for example, they accounted for over 962,000 or nearly half of all deaths that year, and more than twice the number of deaths due to cancer, the next highest cause. Diseases of the heart, lungs, and blood are also major causes of morbidity and loss of productivity: most Americans over the age of 50 will have some degree of arteriosclerosis, about 1,000 people suffer strokes each day, and more than 14 million people are victims of chronic lung disease.

In the face of these challenges, the Institute has accomplished a great deal. An Institute-supported program to detect hypertension is held partly responsible, along with reduced cigarette smoking, for a decrease of 17 percent in death rates due to heart disease and stroke from 1970–1977. Greatly increased understanding of blood clotting mechanisms has helped hemophiliacs, and research knowledge has been applied to help victims of neonatal respiratory distress syndrome.

The National Dental Research Act, also passed in 1948, created the National Institute of Dental Research (NIDR). Perhaps even more than the other Institutes, NIDR has concentrated its efforts in prevention of these costly afflictions under its purview; oral and dental diseases and conditions. In one major undertaking, research sponsored by NIDR has improved understanding of the relationship of fluorides to caries prevention.

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) began as the National Institute of Neurological Diseases and Blindness in 1950. The study of vision was transferred from the Institute in 1968, and in 1975 the name was changed to the current NINCDS, reflecting the importance of research on stroke, the leading cause of death and a major crippler of older Americans. In the research fields supported by this Institute, investigations have led to the development of new drugs for the treatment of epilepsy and Parkinson's disease, helping many thousands to overcome these debilitating diseases. Even so, 25% of epilepsy patients have little or no control over their seizures. Other research sponsored by NINCDS has led to the discovery that certain degenerative neurological disorders of man, such as Kuru and Creutzfeld-Jakob dementia, are caused by slow-acting or latent-type viruses, a finding which could lead to ways of preventing these and other diseases.

The Omnibus Medical Research Act, which created the National Institue of Neurological Diseases and Blindness and gave the Surgeon General the authority to establish new Institutes, created the forerunner of the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) in 1950. Diseases studied with NIAMDD sponsorship include arthritis, related musculoskeletal diseases, diseases of the bone and skin, diabetes and other metabolic and endocrine diseases, digestive diseases, nutritional disorders, and diseases of the kidney and urinary tract. It has been estimated that 22 million Americans suffer from arthritis, making this condition the second ranking cause of morbidity in the United States. Digestive diseases collectively represent 10% of the total economic burden of illness in the United States as defined by the National Center for Health Statistics. In the area of diabetes, a major achievement supported by NIH funds last year was the development of a portable insulin pump system which delivers a continuous supply of insulin to the diabetic patient. This system would not only obviate the need for daily injections by diabetics, but also presumably would reduce the risks of blindness, circulatory failure, and other problems attributed to fluctuating levels of insulin.

In 1955, without benefit of legislative action, expansion of the National Microbiological Institute created the National Institute of Allergy and Infectious Diseases (NIAID) as the sixth National Institute of Health. Research funded by this Institute is responsible for the development of a vaccine against rubella, which, if it infects a pregnant woman, can cause serious malformation of the unborn fetus. Recently, the drug adenine arabinoside was tested as the first successful treatment for patients with viral encephalitis. Development of safe and effective vaccines against influenza still poses a great challenge to NIAID.

Congress established the National Institute of Child Health and Human Development (NICHD) in 1962. With a strong emphasis on primary prevention, NICHD is the focus for NIH of research on child and maternal health. Research is conducted on such conditions as sudden infant death syndrome (SIDS), mental retardation, birth defects and developmental disabilities, as well as population research and contraceptive development. The Institute has made great progress in decreasing the infant mortality rate in the U.S. and in improving our understanding of SIDS. Still, there is much to be learned about what causes congential defects: 7 percent of infants born have some kind of defect and more than half of spontaneous abortions are of deformed fetuses. In the important area of fertility research, more than one-fifth of all births are unwanted, while two million couples who want children are unable to procreate.

In 1962, the Division of General Medical Sciences became the National Institute of General Medical Sciences (NIGMS). This is the only Institute which has as its charge, not the study of a specific set of diseases, but rather the study of the sciences basic to all medicine. Areas of research include the cellular and molecular basis of disease, genetics, pharmacology-toxicology, physiology, and biomedical engineering. As the major Institute funding the basic sciences, NIGMS supported much of the genetic and cellular research that helped lead to the development of recombinant DNA techniques. Many of the diseases

that remain to be conquered arise because of genetic and cellular changes. To understand and prevent these diseases will necessitate an understanding of basic cellular mechanisms, part of the NIGMS mission.

In 1968, the blindness program was split off from the original National Institute of Neurological Diseases and Blindness and, expanded, became the National Eye Institute. Research supported by this Institute studies the normal functioning of the eye, the pathology of visual disorders, and the sciences underlying the study of vision. A major recent accomplishment has been the use of a laser photocoagulation techniques which may decrease by 50–60 percent the occurrence of blindness due to diabetic retinopathy, the leading cause of new blindness.

In 1969, the National Institute of Environmental Health Sciences was to be established. The mission of this Institute is to study the effects of chemical, physical and biological environmental agents on human health. As a result of NIH grants, investigators determined that inhaled asbestos fibers could cause a form of lung cancer, in finding which led to the development of exposure standards for workers in the asbestos industry. According to a recent statement by the Director of NIH, in 35 years, without those standards. 10,000 workers would have died from asbestos-caused disease.

The youngest Institute was created when Congress passed the Research on Aging Act of 1974. The National Institute on Aging (NIA) conducts and makes grants for research on the biomedical, social and behavioral aspects of the aging process and diseases and other special problems of the aged. As such, it is the only Institute whose mandate specifically include social science research. The most important accomplishment of this Institute thus far has been to awaken interest in this neglected field, and to articulate the hope of an old age without disease and infirmity. New theories have been set forth to explain senile dementia, the disease most feared in old age. In addition, NIA has pinpointed the important problem of side effects associated with multiple drug use. It is not uncommon for those above age 75 to have multiple conditions and to take 5 or 6 medications at any one time. The interactions among these drugs are often not known, but in some cases may produce serious symptoms which can be misinterpreted as disease.

The Division of Research Resources, while not actively engaged in research, supports the work of all the other Institutes by meeting their biotechnological, test animal, and other support needs. The Division also provides extramural grants for the support of research activities that cut across Institute boundaries, clinical and laboratory research facilities, computer centers, primate research centers and other resources.

In reflection of the impact of specific diseases on the health of the American people, the two largest of the research institutes are the National Cancer Institute and the National Heart, Lung, and Blood Institute (NHLBI). These two Institutes have in recent years received more congressional scrutiny than has the rest of NIH, including the need for periodic reauthorization. The other Institutes operate directly under the general research authority of Section 301 of the Public Health Service Act. This bill extends the funding for NCI and

NHLBI for three years, through fiscal year 1985, providing budget authority that increases at 6 percent, 5.5 percent, and 5 percent respectively for each of the three years.

In addition, the bill expands Cancer Research and Cancer Control programs to include support for research projects related to "continuing care of the cancer patient and the patient's family." Cancer victims and their families suffer tremendous psychological, economic, and social problems related to their illness. More research is needed on optimal care of the cancer patient during prolonged phases of illness, during terminal stages, and on psychosocial support of families, medical staffs, and patients. Cancer Control programs are authorized to conduct "developmental research" in addition to current programs. This will facilitate identification, field testing, and evaluation of cancer control methods and techniques. Continued maintenance and operation of the International Cancer Research Data Bank, authorized by the National Cancer Act of 1971, is mandated. A special focus is requested on dissemination of cancer research and treatment data, as this information will be of particular value to the 80 countries having access to the Data Bank. The grant cycle for cancer research and demonstration centers is extended from three years to five years. Finally, in both NCI and NHLBI, the Directors may approve grants without advisory board referral if the direct costs do not exceed $50,000 (instead of the current $35,000).

Advisory Boards play an important role in assuring the most effective use and organization of resources for research, treatment, education, and training in particular disease areas. Currently, the National Institutes of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDI) has Advisory Boards for the Diabetes, Arthritis, and Digestive Disease programs, all authorized through 1983. This bill establishes a National Kidney and Urologic Diseases Advisory Boards, and sets the data of expiration of all four Boards at September 30, 1985.

A provision of this bill eliminates the payback requirement for recipients of National Research Service Awards (NRSA's). These awards are for the training of biomedical and behavorial scientists in areas of national need, and take the form of both individual fellowships and institutional fellowships ("training grant"). In 1974 the Congress revised research training authorities and provided specific authorization ceilings. The legislation also included a service payback condition, presumably to make it less suspectible to Presidential disapproval and more acceptable to the public at large. Specifically, the payback requirement was seen as means of preventing misuse of the research training program by individuals seeking subspecialty medical training. Currently, upon completion of training under the program, individuals who receive NRSA support are expected to engage in biomedical research or training for a period equal to the period of support. If an individual fails to fulfill the service or "payback" obligation, the Federal Government is entitled to recover the stipend the individual received from the NIH plus interest beginning not later than two years after the award has terminated. The payback provision has been cited as a significant factor in discouraging young physicians from embarking on a career in research, particularly those

who are unsure whether they wish to pursue that course. In addition, because of this provision, the Internal Revenue Service has ruled that the awards are fully taxable, further discouraging potential researchers from devoting time to training.

A three-year renewal of authority through fiscal year 1985 is made for the Medical Library Assistance Act program of the National Library of Medicine. Since its original passage in 1965, this Act has provided assistance through grants and contracts to health sciences libraries for library resources, research in biomedical communications, training, biomedical publications, and for the support of the Regional Medical Library Network. The activities supported under the Act have resulted in the improvement of medical library services, particularly by fostering cooperation and resource sharing.

The bill replaces the Office of Health Information, Health Promotion and Physical Fitness, and Sports Medicine with an Office of Disease Prevention and Health Promotion in the Office of the Assistant Secretary for Health. Its mandate is to coordinate all DHHS and private sector activities, including information dissemination, in areas related to preventive medicine, health promotion, and physical fitness and sports medicine. Sections relating to project grants for physical fitness improvement and for sports medicine research, which were authorized for fiscal years 1980 and 1981 but never funded, are repealed.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research is extended for two years, through 1984. The Commission was created in 1978 to report to the President and the Congress on the adequacy and uniformity of Federal rules and policies regarding the protection of human subjects of research. It made the first such report in December 1981, and has also prepared a report on the medical, legal, and ethical issues in the determination of death. The Commission is presently scheduled to expire on December 31, 1982. The extension of its mandate would afford the opportunity for further study of the many ethical and legal issues that arise in the course of biomedical research.

The Secretary is required to prepare two new annual reports and transmit them to the appropriate Senate and House Committees. The first is to report on activities undertaken to improve grant, contracting, accountability, and peer review procedures at NIH. Several recent instances of questionable research practices, and in some cases accusations of outright fraud, have led to congressional oversight hearings and unfavorable media coverage. It is important that both the scientific community and the public trusts the integrity and impartialty of research sponsored by NIH. Likewise, procedures for application, peer review, and approval of grants and contracts warrant continued discussion to ensure their fairness to all potential applicants. The second new report is to cover all activities of NIH relating to preventive medicine and health promotion, including the number and type of personnel involved in such activities. This report will complement the Department-wide emphasis on health promotion and disease prevention to be coordinated by the Office of the Assistant Secretary for Health.

A requirement is placed on the Institute Directors to notify their Advisory Boards of the status of any investigation of a recipient,

unless such a disclosure would jeopardize the investigation. With such knowledge, the Board could make a more informed decision on any other applications the individual might have pending for approval.

A final provision concerning grants and contracts is that the NIH Director shall establish procedures for the appeal of determinations made on applications for research funding. Currently, such procedures are not uniform among the various Institutes.

The bill establishes the President's Council for the Health Sciences, a temporary seven-member body with a mandate to spend two years preparing a National Health Sciences Plan. The Plan will set forth long-term priorities for health sciences research, taking into consideration the effects of various diseases on the population, promising areas of research, research priorities of Federal agencies other than DHHS, and needs in underdeveloped research areas. To make the optimum use of scarce resources, some long-range planning to consider national goals is necessary. NIH and individual Institutes have previously developed their own planning document, but there is a need for specific examination of government-wide support for research in the health sciences, including the Veterans Administration, the Department of Defense, the Department of Energy, and the National Science Foundation. Careful analysis is necessary to match needs with opportunities in the various fields of health sciences.

Title II of the bill contains a number of miscellaneous provisions, concerning, among other things, disposition of the former Boston Public Health Service Hospital; authority for nurse anesthetist training; elimination of penalties and extension of deadlines that would interfere with phaseout of health planning programs and State expenditures of already-appropriated fiscal year 1982 funds; clarification of funding for mental health services under the Alcohol and Drug Abuse and Mental Health Services Block Grant; and modification of a requirement of the Community Services Block Grant Act. See Committee Views and the Section-by-Section Analysis for more detail.

III. HISTORY OF S. 2311

A bill, S. 2311, for the purpose of revising and extending programs relating to biomedical research, research training, medical library assistance, health information and promotion, and research ethics was introduced by Senator Hatch on March 30, 1982, and was referred to the Committee on Labor and Human Resources.

Oversight hearings devoted to activities of the National Cancer Institute (NCI) were held by the full Committee on June 2, 1981, and by the Subcommittee on Investigations on May 21, 1981, November 3, 1981, November 6, 1981, and March 5, 1982.

On April 12, 1982, the Committee requested comment on S. 2311 from the Department of Health and Human Services, the General Accounting Office, and the Office of Management and Budget.

On April 27, 1982, the Committee met in open executive session to consider an amended version of the bill which incorporated the recommendations and comments of members of the Committee, professional societies, the Administration, and interested individuals. During the session, three additional amendments were adopted: one by Senator Hatch regarding state health planning; one by Senator Staf-

ford revising the formula for Alcohol and Drug Abuse and Mental Health Services Block Grants; and one by Senator Eagleton amending the Community Services Block Grant Act. Senator Weicker offered an amendment to authorize a revised federal health planning program, which failed on a tie vote of 8 for and 8 against. The bill as amended was ordered reported favorably to the Senate.

IV. HEARING

A public hearing on S. 2311 was conducted by the Committee on March 31, 1982, with the following individuals providing testimony:

Honorable Paul G. Rogers, Hogan and Harston, Washington, D.C., Former Chairman, Subcommittee on Health and the Environment, U.S. House of Representatives.

Edward N. Brandt, Jr., M.D. Assistant Secretary for Health, Department of Health and Human Services; Vincent T. DeVita, Jr., M.D., Director, National Cancer Institute; Peter L. Frommer, M.D., Acting Director; National Heart, Lung, and Blood Institute; Martin M. Cummings, M.D., Director, National Library of Medicine, a panel.

G. Richard Lee, M.D. Dean, University of Utah College of Medicine, representing the Association of American Medical Colleges.

A statement was submitted for the record by Armand Hammer, M.D., Chairman, President's Cancer Panel, who was absent because of illness. Additional statements were received by several health professional and voluntary organizations, and accepted for publication in the hearing record.

V. COMMITTEE VIEWS ON S. 2311

General

The Committee has spent considerable time and effort preparing for the reauthorization of the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the National Library of Medicine Assistance Act. These two institutes, the only ones requiring periodic reauthorization, are the largest of the 11 National Institutes of Health. However, the Committee has used this legislation as an opportunity to consider programs and activities throughout the National Institutes of Health. Consequently, it is intended that these Committee views be considered relevant for all NIH programs, unless otherwise specified.

The National Institutes of Health are indisputably the premier biomedical research complex in the world. Their leadership in medical science developed through the 1960's, and their accomplishments have been translated into improved health care not only for our citizens, but also for mankind in general. Acquisition of new knowledge through basic biomedical research, clinical research, and promotion of that knowledge through technology transfer has improved the quality and longevity of life. The Committee views the government's investment in NIH programs as a highly appropriate federal effort, that overall has proven cost effective. Continuity in the federal investment is a key factor in attracting bright and capable young scientists

to the field of medical science. Accordingly, the Committee emphasizs the need to maintain the current research effort to ensure that the momentum of expanding research efforts in the 1960's not be lost.

Thus, the Committee has authorized funding of the NCI and NHLBI programs at 6 percent over the fiscal year 1982. This level of funding will undoubtedly impose some constraints on new research efforts but should provide the resources to maintain a firm basis of support. The Committee recommends a similar increased level of support for the other institutes and programs at NIH.

Despite the strong support of the Committee for NIH, the Committee recognizes problems do exist. Congressional hearings and investigations over the previous decade have highlighted numerous concerns, many of which have persisted and, unfortunately, become even more troublesome.

The problems which most concerned the Committee include: (1) recent publicity regarding poor management and fraud among scientists whose research is supported by NIH; (2) persistent allegations that the peer review system is inefficient and sometimes unfair, in spite of multiple efforts in recent years to evaluate and improve the system; (3) the increase in indirect costs of grants and contracts which provide institutional support, great variation among research institutes and universities regarding how these indirect costs are calculated, and an Administration proposal that indirect costs be cut 10 percent across the board; (4) inadequate research in preventive medicine and health promotion, with disproportionate funding of rare disease processes; (5) inadequate funding of research equipment, with a rapidly growing obsolescence of scientific instrumentation in most federally funded research laboratories; (6) inadequate funding of prevention treatment and cure of arthritis and musculoskeletal disease; (7) clinical trials with unproven drugs allegedly without sufficient patient education, monitoring, and long-term follow-up of efficacy in all cases; (8) increasing competition and friction among scientists and lay advocates of specific disease or organ system research programs, who seek for targeted funding, or specific legislative emphasis; (9) ineffective coordination and cooperation among some Institutes at NIH and other federal agencies conducting related health research projects.

The Committee chose not to deal with most of these specific problems by legislative mandate. Specifically, the bill does not newly authorize funds devoted to any particular disease-oriented research, nor does it alter the structure or organization of NIH. Some of the concerns are addressed by required annual reports, giving Congress the information needed to determine if future changes in the Act are necessary. The Committee expects other problems will be addressed by the establishment of the President's Council for the Health Sciences. The proposed report from the council should provide essential information regarding future health policy.

Most importantly, primary concerns are relayed to the Administration and NIH officials with the full expectation that efficient and effective solutions will be forthcoming. During the life of this legislation, the Committee intends to schedule additional oversight hearings to ascertain the progress being made to address the above-stated problems, and review additional concerns which may be brought to the

Committee's attention by the public or scientific community regarding NIH research activities. It is the hope of the Committee that this consultation between the Congress and NIH will solve the growing number of problems related to this large federally funded program and will be more effective than extensive statutory changes which may prove overly rigid. This will require ongoing cooperation between NIH and the Committee. If the desired results are not apparent by the next reauthorization cycle three years hence, the Committee may need to consider significant changes in Titles III and IV of the Public Health Service Act in order to guarantee economy and progress in the research effort.

Additional Committee views include: Nutrition, National Institute on Aging (NIA), Indirect Costs, and Research Equipment.

Nutrition

The Committee was pleased to learn that nutrition research is funded by all eleven Institutes and the Division of Research Resources. Nutrition may play a pivotal role in the development of many diseases, including our most debilitating and costly chronic diseases, and the Committee feels it is in the best interest of our citizens to encourage all institutes to emphasize and enhance nutrition-related research relevant to the respective disciplines. One noteworthy example of much needed research relates to nutritional therapy of patients with chronic renal disease. Previous studies suggest renal failure can be substantially retarded by such treatment, and if implemented on a large scale could result in considerable savings to the federal End Stage Renal Disease Program.

National Institute on Aging

The Committee has learned that the National Institute on Aging, the youngest of the Institutes, established in 1973, is making considerable progress in achieving its legislative mandate. Although its budget is modest by comparison with other Institutes, it has succeeded in enhancing the research and education of health professionals throughout the country related to geriatric medicine. The Committee has learned that current research efforts in demetia are hampered by the present location of the Laboratory of Neurosciences in Baltimore, Maryland. Transfer of this research effort to the Bethesda campus would facilitate coordination with complementary research being conducted in National Institute of Neurological and Communicative Disorders and Stroke. The Committee believes this area of research is important and that the cost involved of transferring the Laboratory of Neurosciences would be offset by the significantly enhanced research potential.

Indirect Costs

The great majority of NIH research is conducted at universities throughout the country through the extramural program.

Indirect costs are institutional costs incurred in the support of research projects. For example, they include utility costs, administration, building use, equipment, depreciation, maintenance, and libraries. NIH reimburses institutions for indirect costs by applying the

institution's approved negotiated rate, based on federal audits. The indirect costs are an integral part of the total research endeavor and are necessary for the adequate completion of funded projects.

The Committee expects NIH to reimburse institutions for the indirect costs of research in accordance with negotiated rates. If the Department believes that previously negotiated rates of individual institutions ar too high, the Committee expects the Department to renegotiate those rates on an institution-by-institution basis with consideration of the different indirect cost components.

Research Equipment

The Committee is aware of studies showing critical shortages and obsolescence of research equipment and instrumentation in the biomedical research community and encourages HHS to examine possible solutions, including possible changes in the indirect costs calculation, such as allowable depreciation rates on equipment, which might aid in alleviating this significant problem.

National Cancer Institute:

The NCI is the largest of the NIH institutes, the largest single biomedical research institute in the world. Full Committee oversight hearings held in June of 1981, and Investigation Subcommittee hearings held in May and November of 1981 and March of 1982, brought to light several problems related to fiscal management and research using human subjects. The director of the NCI initiated several activities to answer congressional concerns. Significant progress was reported at Committee reauthorization hearings held March 31, 1982 regarding clinical trials with unproven chemotherapeutic agents, and procedures for awarding grants and contracts. Nonetheless, further improvements in accountability are expected. Based on problems encountered within NCI, the director's of all Institutes would be required by Congress to advise their national advisory boards of any investigation concerning a recipient of a grant or contract, unless those conducting the investigation advise the director that disclosing such information might jeopardize the investigation. It is also expected that other NIH institutes will be notified of individuals under investigation, as appropriate.

The Committee is concerned about the number of reports in the media over the past year revealing fraud and unethical behavior in the biomedical research community, but believes these reports represent a small minority of scientists and should not reflect on the biomedical research community in general. NCI is to be commended for prompt changes in procedures; nonetheless, the NCI, by virtue of its large and diverse research efforts, is expected to continue its vigilance in protecting against fraudulent research activities. In particular, they are expected to improve efficiency and prevent awards being given to applicants who may conduct research outside of highly ethical standards.

Amendments made to the National Cancer Act were directed at important concerns which has strong consensus within the Committee.

Sections 401 and 403 were amended to require research be conducted related to continuing care of the cancer patient and the family of the cancer patient. This addresses the concern that a number of cancer victims suffer tremendous psychological, economic and social problems related to their illness. A growing number of cancer patients seek unconventional and unproven treatments, often at great cost, and requiring travel to foreign countries. Many patients who seek unconventional therapies do so because they have been told nothing more can be done for them with conventional therapy, or because existing therapies are necessarily painful or have side effects. Many health professionals providing conventional therapy are perceived as being judgmental or punitive of the patient who seeks unproven therapies, which likely contributes to cancer patients' seeking whatever treatment might be proffered by supportive practitioners. In particular, more attention is needed regarding why unorthodox treatments are sought by a growing number of cancer victims. Research is needed regarding how optimal care might be provided for the cancer patient during prolonged phases of illness and terminal stages, especially effective treatment of chronic, intractable pain. Research is also needed regarding psycho-social support for families of the cancer patient and for medical staffs caring for terminal patients. The Committee wishes to make clear this amendment is designed to require support for research projects related to continuing care, and not for financial support for long-term care projects.

The Committee is impressed by the progress in cancer research and patient care that has been achieved in cancer centers nationwide. Much of the basic research in cancer, as well as the treatment and prevention of these diseases, is being accomplished in NCI-supported cancer centers. The Cancer Center Support Grants (awarded by the National Cancer Institute to cancer centers) are an important part of the institute's effort; the center core grants are in fact "the glue" that holds grant-supported projects conducted within cancer centers together, and contributes to the effectiveness and efficiency of research. The dollars devoted to cancer centers have increased over the past several years, but the proportion of the total budget devoted to cancer center support has gradually fallen. The Committee urges the NCI leadership to review this trend and maintain support for cancer centers at a level which will ensure their stability.

Section 403 was amended to include developmental research in Cancer Control programs. This will facilitate identification, field testing, and evaluation of cancer control methods and techniques, as well as demonstrations to determine applicability, acceptability, cost-effectiveness, risks, and educational benefit. The Committee wishes to clarify the definition of Cancer Control as constituting those activities which: (1) facilitate the dissemination of existing and new biomedical technology, skills and knowledge from the cancer centers to those providing patient care in the communities, (2) identify cancer control methods and techniques found applicable, and promote appropriate and widespread use of those methods and techniques which prove most effective.

The period of support for cancer centers was increased from three to five years. Experience has shown that three years does not allow a

sufficient time for continuity and adequate long-range planning, and produces wasteful expenditure of funds in terms of personnel and paperwork required.

Section 404 was amended to strengthen the statutory base of the International Cancer Research Data Bank by requiring it be maintained and operated and promote dissemination of treatment data as well as research information. The ICRDB was established through the efforts of Senator Pell in the National Cancer Act of 1971.

Through contacts with scientists here and abroad, the Committee learned there was inadequate sharing of information on cancer research within this country, and even less effective communication between scientists and researchers in other countries. To resolve this, the ICRDB was established. Today its data collection centers in the United States and overseas contain the most current information on research, publications, and treatment protocols.

Section 405 was amended to give the NCI director authority to approve funding of research and training grants up to $50,000, after appropriate review of scientific merit. The previous ceiling of $35,000 for director approval of such grants has proven too restrictive, resulting in overload of the peer review system.

The legislative authority for the National Cancer Advisory Board was left intact. Nonetheless, the Committee is concerned that individuals considered to fill vacancies should include those knowledgeable in environmental carcinogenesis. This has become increasingly more important in our complex society, with new scientific data emphasizing the importance of environmental factors in cancer causation. The Committee is also concerned that prolonged vacancies on the advisory board have a deleterious effect. It is hoped that the President will make appointments within 90 days of an expired term or vacancy, thus facilitating full operating strength of the advisory board. The Committee is aware of concerns that NCAB has been dominated by representatives of professional and institutional interests. In filling vacancies, the Committee encourages appointments, to positions reserved for nonscientists, of individuals with management and policymaking skills. It is hoped that such individuals could contribute to improved management of the grant and contracting procedures.

The legislative authority for the President's Cancer Panel was left unchanged. The Committee has concerns that prolonged vacancies on the panel contribute to less effective performance and it is hoped that the President will fill such vacancies within 90 days of occurrence.

The National Cancer Advisory Board has made approximately eleven reviews of the Organ Site Program over the last decade, all of which have supported continuation of organ site programming. Existing task forces have been very productive, and the most recent review suggested adding new organ site task forces. For example, the work of the Prostate Organ Site program has contributed to prostate cancer becoming one of the more curable malignancies. Approximately $13 million, $5 million less than its peak funding of $18 million, is currently being devoted to the four existing task forces on pancreas, bowel, prostate and bladder. The Committee expects continued funding for these important programs and establishment of the recommended new task forces, as resources permit.

The Committee is impressed that cancer education programs, designed to teach prevention, early detection and diagnosis of cancer to medical and dental students have proven effective. Teaching the bases of coordinated, multidisciplinary cancer management to students will result in improved patient care by health professionals in all disciplines. The Committee expects the NCI will continue funding cancer education programs. However, the Committee is concerned whether NCI should continue to fund a large number of post-doctoral training programs in oncology when the need for these specialists is likely to decline, in view of the Graduate Medical Education National Advisory Council (GMENAC) report projections of imminent physician surplus. It is expected that NCI will consider current and future medical manpower personnel data in determining funds allocated to post-doctoral clinical fellowships, and adjust the level of support to comply with estimated need.

National Heart, Lung and Blood Institute

Few legislative changes were made in the authority for this institute. Health care statistics related to cardiovascular diseases in general are significantly improved for the nation, with mortality from atherosclerotic diseases and cerebrovascular pathology having dropped significantly over the past decade. These improved health statistics constitute a strong justification of the investment of national health care dollars in research and community screening projects funded through the National Heart, Lung and Blood Institute. Specifically, the hypertension detection and follow-up program is an example of praiseworthy cooperation between the federal government, local governments, voluntary organizations, and health professional organizations. This large-scale community-based outreach program has proven highly cost-effective, and provided valuable data regarding treatment of hypertension and its impact on morbidity and mortality.

In view of increasing data relating lifestyle and stress to cardiovascular diseases, the Institute is to be commended for establishing a Branch of Behavioral Medicine. However, recognizing the magnitude of the problem, the Committee believes this effort is inadequate, and the Committee encourages expansion of research and community projects related to behavioral medicine.

Section 413 was amended to highlight the importance of research in hemolytic diseases such as sickle cell anemia and Cooley's anemia. Sickle Cell anemia remains a serious health problem to a significant portion of the black population and merits receiving continued strong support. In particular, continued support for the 10 existing Comprehensive Sickle Cell centers is considered important to the overall sickle cell anemia research program.

The Director of the National, Heart, Lung and Blood Institute is given the authority to approve grants not exceeding $50,000, instead of the current $35,000 ceiling, thus recognizing that inflation has diminished the size of projects conducted with this amount of money.

The Committee has learned that there may be significant overlap of research related to lung disease and hematologic diseases within the National Institutes of Health. For example, the Division of Blood

Diseases and Resources of the NHLBI is most concerned with fundamental hematologic research and its clinical applications; however, research conducted in the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases emphasizes the mechanism of normal blood cell function and its alteration in disease processes. Also, the National Cancer Institute is involved in research on malignant alterations of blood cells and treatment of these disorders. The Committee expects that such a broad range of hematologic research will continue to be supported, and directs NIH to coordinate the direction of such research.

The Committee has also learned that research in lung diseases is supported by several institutes within NIH, as well as by other government agencies including the Veterans Administration, the Department of Defense, and the Environmental Protection Agency. Because of the large number of agencies expending funds and energies on programs devoted to pulmonary research, the Committee is concerned that duplition and/or omission of important research areas may occur. The need for coordination of this effort is essential. The currently existing Interagency Committee on Heart, Blood Vessel, Lung and Blood Diseases has a broad mandate, but has not been successful in providing the desired coordination regarding lung research. The Committee is concerned that this existing Interagency Committee should focus on coordination of lung research, thus providing the necessary information to assure the public that federal funds spent on lung research are applied in the most efficient manner. It is hoped that the Interagency Committee might accomplish this without additional administrative costs. The Committee anticipates that a federal government-wide coordination of health research will be facilitated by recommendations of the President's Science Health Council, also authorized by this legislation.

The Committee has learned of a private initiative to aid in the treatment of Fanconi's anemia, a rare congenital hematological disease which is fatal, due to bone marrow failure and a high incidence of malignancy. Effective treatment of the associated iron excess has been developed, and could be available at many medical centers in the country. However, more information is required regarding the prevalence of this disease. Research regarding the mechanism of action and more definitive therapy is needed for Fanconi's anemia, and other asplastic anemias.

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases

During the development of this legislation, several special interest groups, including health professional conducting extramural research and volunteer organizations representing patients with specific organ system pathology or diseases, expressed concerns that the research effort devoted to their interest was inadequate. It is apparent that considerable friction and competition for federal support exists, fueled by perceived inequities, some of which may be real. For example, the Arthritis Foundation, supported by physician/scientist specialists in rheumatology has proposed the establishment of a national arthritis

institute to facilitate a more effective research effort in arthritis and musculoskeletal disease, justifying this proposal on the prevalence of these diseases and the extraordinary economic impact secondary to their related disability. Likewise the Juvenile Diabetes Foundation has advocated a separate institute devoted to diabetes research. During the course of hearings on this legislation, the Committee relayed to the Administration the concerns brought forward by the Arthritis Foundation that research devoted to arthritis and musculoskeletal diseases is inadequate, and requested administrative changes to address this problem. DHHS responded with the announcement that NIADDKD would be reorganized, with the elevation of current disease clusters to separate divisions status, resulting in more efficient management and an improved research effort for each of these categories. Consequently, the Committee did not mandate legislative restructuring of this institute at this time, and would like to avoid this result if possible because of the NIH resources which would be taken away from research to accomplish the restructuring. However, the Committee expects the Secretary to report back to the Committee on the effect of the NIADDKD restructuring, and to evaluate the degree to which the restructuring has addressed the perceived inequities.

Other Concerns Addressed by the Committee

1. A need to coordinate research conducted in skin diseases throughout the National Institutes of Health, as well as the National Institute for Occupational Safety and Health. Occupational skin diseases reportedly account for 45 percent of all occupational illness and 25 percent of time lost from work secondary to such illnesses. Also, because skin research is conducted throughout NIH, improved coordination of these activities is necessary. Thus, the Committee intends that the director of NIH should establish within NIADDKD an Interagency Skin Disease Coordinating Committee. Appropriate representatives from each of the NIH Institutes conducting skin-related research as well as a representative from NIOSH should be included. Principal functions of this committee would be coordination of inter-institute and inter-agency skin-related research and development of a coordinated plan identifying priorities for new research initiatives in skin diseases.

2. The Committee has heard of considerable concerns expressed by the digestive diseases research community regarding inadequate epidemiological data. Insufficient attention to such research related to digestive diseases is unfortunate in view of the prevalence and disability associated with these illnesses. Advocates for patients suffering from digestive disorders, as well as the research community, have recommended establishing research centers similar to those which have proven successful in facilitating research in other specific health problems, i.e., cancer centers, arthritis centers. Such centers can facilitate economic research by enhancing cooperation within institutions, sharing existing resources, and improving communication. The Committee recommends NIADDKD consider development of such centers supporting digestive disease research as recommended by the Digestive Disease Advisory Board, with consideration of resources available and continuating of funding the recommended level of research grants.

3. The epidemic of sexually transmitted diseases is of concern to this Committee. The Center for Disease Control estimates that one out of every 4 Americans between 15 and 55 years of age is effected by a venereal disease, and these diseases have serious impact on reproduction, fertility and infants.

The Committee is concerned that inadequate priority is accorded research in this area, and believe that it is important to strengthen basic and clinical investigation in sexually transmitted diseases.

National Research Service Awards

Section 472 was amended to repeal the payback requirement for recipients of National Research Service Awards, which has required individual to devote a specified amount of time to research, teaching, or providing health service in a designated medical manpower shortage area. There has been a remarkably low incidence of recipients of such research service awards failing to comply with requirements and concern has been frequently voiced from the scientific community that the payback requirement may function as a disincentive to some young scientists pursuing a career in biomedical research. Also, the cost of tracking recipients of these research service awards and determining compliance with federal regulations is considerable, exceeding $350,000 per year. The Committee feels this money can be better spent in supporting the young scientists by funding additional research service awards. Nonetheless, it is expected that the impact of this deregulation will be assessed, and data provided to Congress, three years after enactment of this legislation, regarding number of individuals seeking USRA's, background training of these individuals, and trends regarding career choice.

National Library of Medicine

The National Library of Medicine Assistance Act was reauthorized, recognizing the importance of this program in training individuals in medical library science. In view of rapidly expanding technology related to the communication of information, the Committee believes training such individuals essential. Indeed, information sciences in general are likely to undergo revolutionary changes in the coming decade as part of already developed and developing technologies which are altering the way information is stored, retrieved, and transferred. The Committee expects that the Library of Medicine will devote more of its energies to incorporating these new technologies and facilitating training of the appropriate information specialists to ensure maximum efficiency and economy in the transfer of health information.

The Committee also appreciates the value of regional medical libraries and recommends continued support of the regional libraries with grants and contracts to the extent possible within current funding levels.

Health Information and Health Promotion

Title XVII of the Public Health Service Act was amended to establish the Office of Disease Prevention and Health Promotion within the Office of the Assistant Secretary for Health. The amendments made to

this section were designed to provide greater focus on activities directly related to preventive medicine and health promotion, and ensure that funds authorized for these activities be devoted to ensuring optimal transfer of health information to our citizens, cooperation with the private sector in health promotion, and coordination of related activities throughout the federal government.

REPORTS

The Committee requests a report January 1983, and annually thereafter, from the Director of NIH regarding activities undertaken to improve grant, contracting, accountability, and peer review procedures of the NIH. Problems related to these areas have persisted for several years, and the growth of Institutes in size and expenditures mandates ongoing efforts to improve economy and accountability. This report should provide information regarding complaints related to these activities, in order of magnitude, as well as new activities implemented to address concerns. The Committee expects to examine these reports carefully since they cover a critical area which may be the basis for further oversight of NIH.

The Committee also requests by January 1984, and annually thereafter, a report regarding all activities at the National Institutes of Health relating to preventive medicine and health promotion including number and type of personnel involved. Many critics of the NIH have suggested a disproportionate amount of time and effort is devoted to research focused on treatment of disease, particularly pharmacotherapeutics, at the expense of research on preventive medicine and health promotion which may realize greater gains in both economic and health terms.

The Committee recommends that appropriate research be devoted to preventive medicine and health promotion in each of the Institutes. The Committee recognized that some Institutes have already improved these research efforts, and they are to be commended. The Division of Resources, Centers, and Community Activities within the NCI has been charged with providing improved epidemiological data relating to cancer. This is important in view of increasing evidence linking environmental factors and cancer causation. The Committee is pleased that an improved research effort is being devoted to nutritional aspects of cancer causation and treatment and believes this area of research merits ongoing emphasis.

Considerable concern was expressed to the Committee regarding increase in fraud and misuse of federal funds by biomedical scientists. Several media articles highlighted the purported increase of fraud in the scientific community, and although there is a definite problem, the Committee believes the actual incidence of unethical behavior among research scientists is low. Nonetheless, to improve accountability, and minimize abuse of federal research dollars, the directors of each Institute are required to notify the advisory board of the respective institute on the status of any investigation conducted by the NIH. Also, the Director of the National Institutes of Health is required to establish procedures for the appeal of determinations made with respect to applications for grants and cooperative agreements for biomedical

research under the Public Health Service Act. Establishment of such procedures is likely to minimize allegations of unfair determinations and discrimination which have been expressed to the Committee.

The President's Council for Health Science is established for a single two-year period to study and report on the long-term health research goals of the nation and coordination of government-wide health research. The Committee believes an independent committee is needed to obtain objective information from which to develop national health research priorities. The President shall appoint the seven members, of which four are required to be individuals distinguished in biomedical and behavioral sciences. In formulating the report recommending long-term priorities for health sciences research, the Committee believes it essential that the council identify, and thereby facilitate coordination, of health sciences research throughout the federal government, and make recommendations to facilitate improved coordination. As cited above in the Committee report relating to the NHLBI and NIADDKD, there is considerable overlap and lack of coordination relating to lung diseases and skin diseases. Although interagency coordinating committees are authorized by statute for arthritis, diabetes mellitus, and digestive diseases, the Committee has learned that they have had limited effectiveness in coordinating activities conducted in multiple federal agencies. It is essential that the newly authorized President's Health Science Council document the extent of duplicative federal research and identify any underdeveloped areas of research which show great promise.

Nurse Anaesthetists

The Committee has approved authorization of nurse anaesthetist traineeships, formerly authorized under Section 831 of the Public Health Service Act. Nationwide, nurse anaesthetists administer approximately 50 percent of all anaesthesia, and particularly rural and small hospitals of fewer than 100 beds benefit from their services. The funds authorized will help ameliorate the current supply shortage of these health professionals, estimated to exceed 5,000 by manpower studies.

Health Planning

If the federal health planning process expires on September 30, 1982, without being renewed, there are two unintentional negative consequences:

(a) States without fully-designated state agencies will lose 25 percent of their Pubic Health Services monies in January 1983 (i.e. as of May 1982, probably all states except Arkansas, New Jersey, Washington, Delaware and New Mexico);

(b) Statutory deadlines of approximately January 1983 exist for complying certificate of need programs and for conditionally-designated state agencies, with an unknown penalty for non-compliance. This may disrupt state-expenditure of already appropriated fiscal year 1982 planning funds (available for expenditure July 1, 1982 to June 30, 1983) before state legislature meet in 1983.

Problem (a) is solved by repealing the sanction to avoid unfairly damaging other recipients of PHS grants (including through block grants). Problem (b) is solved by extending the deadlines to approximately June 30, 1984.

Explanatory note.—Public Law 96–79 at section 129 contained instructions regarding the effective dates of certain amendments made by that law. Section 129 did not, itself, amend Title XV and therefore to change the instructions it is required that section 129 be amended rather than a section of Title XV.

Community Services Block Grant

The Community Services Block Grant, enacted as a part of reconciliation last year, turned over to the states the community action program formerly operated by the Community Services Administration. Under the terms of reconciliation, for fiscal year 1982 only, state applications for Community Services Block Grant funds must specify that at least 90 percent of allotted funds will "pass through" to community action agencies, limited purpose agencies that perform functions similar to community action agencies, or migrant and seasonal farmworker organizations. For fiscal year 1983, and thereafter, the CSBG requires a 90 percent pass-through to local units of government, private nonprofit community organizations, or migrant and seasonal farmworker organizations.

This Committee amendment would extend 90 percent pass through to community action agencies for an additional 6-months, through the first two quarters of fiscal year 1983, with a conforming amendment to insure a 90 percent pass through to local government, community agencies, or migrant and seasonal farmworkers thereafter.

The CSBG also provided states with the option of delaying assumption of the new Community Services Block Grant for fiscal year 1982.

In the first quarter of fiscal year 1982, 43 states and territories opted into the Community Services Block Grant, but virtually none of the largest states—New York, California, Texas—did. Thus, although 43 states and territories decided to operate the block grant program, approximately 50 percent of the total community services funds continue to be run in a direct federal-local grantee relationship.

In testimony before the Senate Governmental Affairs Committee, the Comptroller General of the United States stressed that a key factor in helping facilitate the transition for most of the block grants is "the states considerable involvement in the predecessor categorical programs. To the extent this involvement existed, administrative frameworks and institutional knowledge were in place." The Comptroller went on to say that continuation of federal outlays from past commitments has proven to be a transition aid.

The Community Services Block Grant is distinguishable from the other grants this Committee approved. Categorical funds included in the Community Services Block were provided directly by the Federal Government to the Community Action Agencies or other local grantees. In contrast, social services and low income energy assistance already flowed exclusively through the states, and Maternal and Child Health, Preventive Health, and Alcohol, Drug Abuse, and Mental

Health programs had substantial state involvement through developing comprehensive state plans and direct program involvement.

This Committee amendment is designed to facilitate transition to the Community Services Block Grant by insuring that grantees of the predecessor program continue to receive funds under the block for six months, allowing states sufficient time to develop an administrative and programmatic framework.

VI. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., May 14, 1982.

Hon. ORRIN G. HATCH,
Chairman, Committee on Labor and Human Resources, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has prepared the attached cost estimate for S. 2311, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1982, as ordered reported by the Senate Committee on Labor and Human Resources, April 27, 1982. As the CBO has not yet received the final language for the bill, this estimate is based on a draft provided by the Committee staff on April 30, 1982.

Should the Committee so desire, we would be pleased to provide further details on the attached cost estimate.

Sincerely,

ALICE M. RIVLIN, *Director.*

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

MAY 14, 1982.

1. Bill number: S. 2311.

2. Bill title: The Biomedical Research, Training, and Medical Assistance Amendments of 1982.

3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on April 27, 1982. CBO has received several draft copies of S. 2311 from the Committee staff. This estimate is based on an undated draft received by CBO on April 30, 1982. The Committee staff has not verified that this is the final draft.

4. Bill purpose: This bill amends Titles III, IV, VII, and VIII of the Public Health Service Act to extend current authorizations and establish new authorizations. Specifically, the bill would extend for three years authorizations relating to the National Cancer Institute, the National Library of Medicine, the Heart, Lung and Blood Institute, and health information and health promotion. The bill would extend for two years authorizations relating to the President's Commission for the Study of Ethical Problems and nurse anesthetists training. The bill would also establish a new authorization for a President's Council on Health Sciences.

5. Cost estimate:

AUTHORIZATION LEVELS[1]

[By fiscal year, in millions of dollars]

	1983	1984	1985	1986	1987
National Cancer Institute:					
Cancer control programs (410(b))	58.6	61.9	65.0	----	----
Other programs (410(a))	916.8	967.2	1,015.6	----	----
Heart, Blood Vessel, Lung, and Blood Disease programs:					
Prevention and control programs (414(b))	38.2	40.3	42.3	----	----
Other programs (419(b))	525.6	554.5	582.4	----	----
National Library of Medicine (390(c))	8.0	8.5	9.0	----	----
Health Information and Health Promotion (1701(b))	2.3	2.4	2.5	----	----
President's Commission for the Study of Ethical Problems (1804(b))	1.1	1.1	----	----	----
President's Council for Health Sciences (481)	----	.8	.8	----	----
Nurse Anesthetists (831(b))	.4	.8	----	----	----
Total, authorization levels	1,551.0	1,637.5	1,717.6	----	----

[1] Authorization levels specified in the bill have been rounded.

ESTIMATED OUTLAYS

[By fiscal year, in millions of dollars]

	1983	1984	1985	1986	1987
National Cancer Institute:					
Cancer control programs (410(b))	31.7	55.8	62.7	29.6	5.0
Other programs (410(a))	456.0	872.6	979.4	461.8	78.7
Heart, Blood Vessel, Lung, and Blood Disease programs:					
Prevention and control programs (414(b))	20.1	36.2	40.8	19.9	3.5
Other programs (419(b))	276.5	497.7	562.1	273.5	47.5
National Library of Medicine (390(c))	5.6	7.8	8.7	2.6	.6
Health Information and Health Promotion (1701(b))	2.1	2.3	2.5	.3	----
President's Commission for the Study of Ethical Problems (1804(b))	.8	1.1	.3	----	----
President's Council for Health Sciences (481)	----	.6	.8	.2	----
Nurse Anesthetists (831(b))	.1	.5	.4	.1	.1
Total, estimated outlays	832.9	1,474.6	1,657.7	788.0	135.4

Note: The costs of this bill fall within function 550.

6. Basis for estimate: This estimate is based on an undated draft of the bill that CBO received from the Committee on April 30, 1982.

All authorization levels are stated in the bill. Authorized amounts are assumed to be fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of appropriate recent program data.

In addition to extending certain current authorizations, this bill would establish a President's Council for the Health Sciences. The Council would prepare a National Health Science plan to establish long-term priorities for health sciences research. The Council would terminate on the last day of 1984.

This bill would also amend the Public Health Service Act. Primary Care and Research Demonstration Grants would no longer be limited to non-urbanized areas. In addition, this bill would repeal a provision of the Omnibus Reconciliation Act (Public Law 97–35) that terminated funding for these grants at the close of fiscal year 1982.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate preared by: Hinda Ripps.

10. Estimate approved by:

C. G. Nuckols,
(For James L. Blum,
Assistant Director for Budget Analysis.)

VII. REGULATORY BURGET STATEMENT

The Committee has determined that there will be minimal increase in regulatory burden of paerwork imposed by this bill. The creation and function of the President's Council for Health Sciences Research will require no new regulations or paperwork on the part of the Executive Branch, or the public. It will publish one report at the end of its two year term.

The revision of statutory authorities within the NIH can be accomplished within present regulations.

VIII. TABULATION OF VOTES CAST IN COMMITTEE

The motion to favorably report the bill to the Senate was passed unanimously by voice of the Committee.

IX. S. 2311—BIOMEDICAL RESEARCH, TRAINING, AND MEDICAL LIBRARY ASSISTANCE AMENDMENTS OF 1982

As reported by the Senate Committee on Labor and Human Resources

Section-by-Section Analysis

Section 1 of the bill cites the Act as the "Biomedical Research, Training, and Medical Library Assistance Amendments of 1982".

Section 2 of the bill identifies all references in the bill as being made to provisions of the Public Health Service Act (PHSA), except as otherwise specifically provided.

Title I—National Institutes of Health

Section 101 of the bill amends various sections of Title IV of the PHSA pertaining to cancer programs. It amends section 401(a)(1) to require the Secretary to conduct and promote research, investigations, experiments, and studies relating to the continuing care of cancer patients and their families. It also amends section 401(b)(1) to remove some of the restrictions on purchase of radium by the Secretary. Section 403 is amended to add developmental research to the list of Cancer Control program responsibilities, and to conform to section 401 with respect to programs to support the continuing care of the cancer patient. Section 404, outlining the duties of the Director of the National Cancer Institute (NCI) in carrying out the National Cancer Program, is amended in subsection (a) to require the continued maintenance and operation of the International Cancer Research Data Bank, and to add a new paragraph requiring the NCI Director to advise the National Cancer Advisory Board of the status of any investigation of any NCI grant or contract recipient, unless such disclosure would jeopardize the investigation. Section 404(b) is amended to require the NCI Director to consult with the Secretary regarding the appointment of advisory committees and the awarding of construction grants. Section 405, concerning scientific review of NCI research grants and programs, is amended to allow the NCI Director to approve grants without advisory board recommendation if the direct costs do not exceed $50,000 (instead of the current $35,000). Section 406, concerning National Cancer Research and Demonstration Centers, is

amended to extend from three years to five years the maximum period for both the initial support and any extension of that support of cancer centers. Section 410 is amended to extend the authorization of appropriations for NCI as follows: for programs other than Cancer Control Programs, $916,801,420 for fiscal year 1983, $967,225,498 for fiscal year 1984, and $1,015,586,772 for fiscal year 1985; for Cancer Control Programs; $58,642,380 for fiscal year 1983, $61,867,710 for fiscal year 1984, and $64,961,096 for fiscal year 1985.

Section 102 of the bill amends various sections of Title IV of the PHSA concerning heart, blood vessel, lung, and blood diseases research programs of the National Heart, Lung, and Blood Institute (NHLBI). Section 413, concerning the National Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources Program, is amended in subsection (a) to include research and study programs on Cooley's anemia. Subsection (b) is amended to delete a provision that requires the NHLBI Director to include projected personnel requirements and recommended funding levels in the annual five-year Program plan. Section 415(b), concerning cooperative agreements for developing National Research and Demonstration Centers for Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources, is amended to require the Director to consult with the National Heart, Lung, and Blood Advisory Council concerning the extension of support for such centers. Section 419A(c), concerning administrative procedures for NHLBI research grant approval, is amended to allow the NHLBI Director to approve grants without Advisory Council recommendation if the direct costs do not exceed $50,000 (instead of the current $35,000). Section 414(b) is amended to extend the authorization of appropriations for heart, blood vessel, lung, and blood disease prevention and control programs as follows: $38,160,000 for fiscal year 1983, $40,258,800 for fiscal year 1984, and $42,271,740 for fiscal year 1985. Section 419B is amended to extend the authorization of appropriations for the rest of NHLBI programs as follows: $525,614,780 for fiscal year 1983, $554,523,592 for fiscal year 1984, and $582,449,772 for fiscal year 1985.

Section 103 of the bill amends section 437 of the PHSA, which establishes the arthritis, diabetes, and digestive diseases advisory boards, by adding a provision for the establishment of a National Kidney and Urologic Diseases Advisory Board. The expiration date of each Advisory Board is extended to September 30, 1985.

Section 104 of the bill makes technical and conforming amendments to various sections of the PHSA. The following sections are amended to replace references to the "Surgeon General" with references to "the Secretary": section 422, concerning dental disease research and training; section 423, concerning the administration of dental research grants and projects; section 424, concerning functions of the National Advisory Dental Research Council; section 431(a) and (b), concerning the establishment of research Institutes; section 432(a) and (b), concerning the establishment and expansion of functions of National Advisory Councils; section 433, concerning the functions of the research Institutes; section 441, concerning the establishment of the National Institute of Child Health and Human Development (NICHD); section 442, concerning the establishment of the National

Institute of General Medical Sciences (NIGMS); section 443(a), (b), and (c), concerning the establishment, composition, and functions of advisory councils; and section 445, concerning the preservation of existing authority of the Secretary. Technical amendment is also made to section 463(b), concerning functions of the National Institute on Aging, to replace a reference to the former Department of Health, Education, and Welfare with a reference to the Department of Health and Human Services (DHHS).

Title II—Other Programs

Section 201 of the bill repeals section 472(c) of the PHSA, concerning the service or "payback" obligation of National Research Service Award recipients.

Section 202 of the bill amends two sections under Title III of the PHSA concerning the National Library of Medicine (NLM) and assistance to medical libraries. Section 383(b) is amended by deleting the requirement that the Secretary include in his annual report to Congress a statement covering the NLM Board of Regents' recommendations on Library policy. Section 390(c) is amended to extend the authorization of appropriations under the Medical Library Assistance Act as follows: $8,000,000 for fiscal year 1983; $8,500,000 for fiscal year 1984; and $9,000,000 for fiscal year 1985.

Section 203 of the bill amends various sections of Title XVII of the PHSA concerning health information and health promotion. Section 1701(a) is amended to provide for the establishment of an Office of Disease Prevention and Health Promotion within the Office of the Assistant Secretary for Health. This new office replaces the current Office of Health Information, Health Promotion and Physical Fitness and Sports Medicine. It is charged with coordinating DHHS and private sector activities in health information and health promotion, preventive health services, and education in the appropriate use of health care; establishing a national health information clearinghouse; and supporting projects, conducting research, and disseminating information relating to preventive medicine, health promotion, and physical fitness and sports medicine. The Secretary is required to cooperate with health care providers, educators, voluntary organizations, and businesses to encourage the dissemination of health information and health promotion activities. Section 1701(b) is amended to extend the authorization of appropriations for this section as follows: $2,300,000 for fiscal year 1983; $2,426,500 for fiscal year 1984; and $2,547,825 for fiscal year 1985. The following five sections are repealed: Section 1706, concerning the Office of Health Information, Health Promotion, and Physical Fitness and Sports Medicine; Section 1707, concerning project grants to State councils on physical fitness for physical fitness improvement; Section 1708, concerning project grants for physical fitness improvement and research projects; Section 1709 concerning a national program for sports medicine research; and Section 1710, concerning a conference on education in lifetime sports.

Section 204 of the bill amends section 1804 of the PHSA to extend the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research until December 31, 1984. Author-

ization of appropriations for the Commission is extended as follows: $1,100,000 for fiscal year 1983 and $1,100,000 for fiscal year 1984.

Section 205 of the bill has two subsections making changes in Title IV of the PHSA, and two additional subsections on matters that are not amendments to existing law. Section 205(a) of the bill amends section 475 of the PHSA, concerning peer review of grant applications and contract projects, to require the Secretary to prepare and transmit to the appropriate committees of Congress an annual report on activities undertaken to improve grant, contracting, accountability, and peer review procedures at NIH. Section 205(b) of the bill adds two new sections to the PHSA: new section 480, requiring the Secretary to prepare and transmit to the appropriate committees of Congress an annual report on activities at NIH relating to preventive medicine and health promotion, including the number and type of personnel involved; and new section 481, requiring the Directors of the NIH Institutes to notify their Advisory Boards of the status of any investigation of a grant or contract recipient, unless such a disclosure would jeopardize the investigation. Section 205(c) of the bill requires the Director of NIH to establish procedures for the appeal of determinations made on applications for research funding.

Section 205(d) of the bill establishes the President's Council for the Health Sciences, setting form requirements for the seven Presidentially-appointed members and making provision for their compensation. Further, it requires the Council, in consultation with the Secretary and the Assistant Secretary, to prepare a National Health Sciences Plan, and to submit it by October 30, 1984, to the President. The President must transmit the Plan, unrevised but with appropriate comments, to the Congress by December 31, 1984. The Plan is to set forth long-term priorities for health sciences research, taking into consideration the effects of various diseases on the population, promising areas of research, research priorities of Federal agencies other than DHHS, and needs in underdeveloped research areas. The Council is also authorized to hold hearings, request information from other agencies, and publish reports of its activities. The Secretary is authorized to assist the Council by appointing personnel, procuring services, including financial and administrative services, and by requesting detail of personnel from other agencies. To carry out this subsection, the following appropriations are authorized: $750,000 for fiscal year 1983 and $750,000 for fiscal year 1984. The Council is to terminate on December 31, 1984.

Title III—Miscellaneous Provisions

Section 301 of the bill makes three technical changes in Title VII of the PHSA concerning health professions training. Subsection (a) amends section 737(2) to clarify a definition concerning the Federal program of insured loans to graduate students in health professions schools. Subsection (b) amends section 781(a)(2) concerning area health education centers. Subsection (c) amends section 791A(b)(3) concerning traineeships.

Section 302 of the bill amends section 340(g) of the PHSA concerning funding for primary care research and demonstration projects.

Section 303 of the bill allows the Secretary to transfer to the Allston-Brighton Community Development Corporation property formerly

belonging to the Boston Public Health Service Hospital, and to authorize the Corporation to use up to $300,000 of already-appropriated funds for the transfer.

Section 304 of the bill amends section 831(b) of the PHSA to extend the authorization of appropriations for training of nurse anesthetists as follows: $400,000 for fiscal year 1983 and $800,000 for fiscal year 1984.

Section 305 of the bill amends section 1521 of the PHSA, concerning designation of State health planning and development agencies, by eliminating the penalties and extending the deadlines by which States must have fully designated agencies. A similar amendment concerning the deadlines is made to section 129(b)(2) of the Health Planning and Resources Development Amendments of 1979.

Section 306 of the bill amends section 1912(b) of the PHSA to clarify the funding for mental health services under the Alcohol and Drug Abuse and Mental Health Services Block Grant. The amendment is to take effect on October 1, 1982.

Section 307 of the bill amends section 675(c)(2)(A) of the Community Services Block Grant Act (Subtitle B of Title VI of the Omnibus Budget Reconciliation Act of 1981) to extend for six months certain requirements for grants.

X. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

Section 1. This Act may be cited as the "Public Health Service Act."

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

Part D—Primary Health Care

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Subpart IV—Research and Demonstration Projects in Primary Care

PRIMARY CARE RESEARCH AND DEMONSTRATION PROJECTS

Sec. 340.[1] (a) The Secretary may make grants to, and enter into contracts with, public and private entities—

[1] Effective October 1, 1982, Section 340 is repealed.

(1) to demonstrate new and innovative methods for the provision of primary health services and dental health services, or

(2) to conduct research on such methods or on existing methods for the provision of primary health services and dental health services,

to medical underserved populations or to such other poulations as the Secretary determines are necessary to demonstrate or conduct research on particular methods.

(b) Grants and contracts may be made under subsection (a) to demnostrate and conduct research on—

(1) methods of attracting and retaining primary care physicians, dentists, physician assistants, nurse practitioners, and other healthp rofessionals, both individually and as teams, to train and practice among medical underserved populations;

(2) differing types of organizational models and relationships including federations of health service centers, designed to meet unique primary health and dental health service needs;

(3) management and technological improvements (including new or improved methods for biomedical communication and medical and financial recordkeeping and billing systems) to increase the productivity, effectiveness, efficiency, and financial stability of primary health and dental health service providers;

(4) methods of providing health promotion, disease prevention, and health education programs, including school health programs;

(5) methods of identifying, coordinating, and integrating existing primary health and dental health service programs with mental health and social service programs to maximize use of available resources, avoid duplication of effort, and ensure a coordinated, comprehensive care system;

(6) specific services or mixtures of services appropriate for a given area, including ambulatory care, home health care, environmental health services (described in section 330(a)(4)), community outreach activities, transportation services, and other supplemental health services (as defined in section 330(b)(2));

(7) the effect of availability of primary health and home health services in terms of reduction of emergency room visits, hospitalizations, and institutionalization in long-term care facilities;

(8) the use of mobile health screening clinics to provide preventive health care services to meet the needs of medical underserved populations; and

(9) such other projects as the Secretary determines to be necessary to further the purposes of this section.

(c)(1) The Secretary may not make a grant or enter into a contract under this section for a project if the project can be carried out under the authority of any other provision (other than section 301, 304, or 305) of this Act.

(2) The Secretary shall, to the extent feasible, coordinate demonstration and research projects carried out under this section with any demonstration and research projects carried out under the Social Security Act for the reimbursement of services which are the subject of projects under this section.

(d)(1) No grant may be made under this section unless an application therefor is submitted to, and approved by, the Secretary. Such

an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe.

(2) The amount of any grant or contract under this section shall be determined by the Secretary.

(3) The Secretary may make payments under this section in advance or by way of reimbursement, and at such intervals and on such conditions as the Secretary may find necessary.

(e) The Secretary shall submit an annual report to Congress not later than March 1 of each year (beginning with 1979) describing—

(1) the projects conducted under this section during the fiscal year ending in the previous year and why they could not be assisted under the authority of other provisions of this Act;

(2) the amount of funds expended in such fiscal year for each project area set forth in subsection (b) and, if more than 20 per centum of the amount appropriated for this section was expended on any single such project area, the reasons for such concentration of expenditures; and

(3) any recommendations resulting from the conduct of such projects.

In the first such report, the Secretary shall include the number of demonstration projects which were funded under section 1110 of the Social Security Act during the fiscal year ending September 30, 1978, which were related to health services in rural medical underserved areas, and which could have been assisted under this section during the fiscal year ending September 30, 1979, but for subsection (c)(1) of this section.

(f) As used in this section, the term "medical underserved population" has the meaning given such term in section 330(b)(3).

(g)(1) There are authorized to be appropriated for the purposes of funding grants and contracts under this section in areas that are not urbanized areas (as defined by the Census Bureau) $18,000,000 for the fiscal year ending September 30, 1979, $20,000,000 for the fiscal year ending September 30, 1980, and $22,000,000 for the fiscal year ending September 30, 1981.

(2) There are authorized to be appropriated for the purposes of funding grants and contracts under this section in urbanized areas (as defined by the Census Bureau) $4,000,000 for the fiscal year ending September 30, 1979, $4,500,000 for the fiscal year ending September 30, 1980, *and* $5,000,000 for the fiscal year ending September 30. 1981. [, and $3,000,000 for the fiscal year ending September 30, 1982]

No funds may be appropriated under this paragraph or paragraph (1) for a fiscal year beginning after September 30, 1982.

(3) There are authorized to be appropriated for the purposes of funding grants and contracts under this section $3,000,000 for the fiscal year ending September 30, 1982.

[(3)] (4) The authority of the Secretary to enter into contracts under this section shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

[(4)] *(5)* The Secretary may continue to support, out of funds appropriated under this section, those demonstration projects which

were funded under section 1110 of the Social Security Act during fiscal year ending September 30, 1978, and which are related to health services in rural medical underserved areas, but only if such projects can not be carried out under the authority of any other provision (other than section 301, 304, or 305) of this Act.

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PART I—NATIONAL LIBRARY OF MEDICINE

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BOARD OF REGENTS

SEC. 383. (a) There is hereby established in the Public Health Service a Board of Regents of the National Library of Medicine (referred to in this part as the "Board") consisting of the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Department of Medicine and Surgery of the Veterans' Administration, the Assistant Director for Biological and Medical Sciences of the National Science Foundation, and the Librarian of Congress, all of whom shall be ex officio members and ten members appointed by the Secretary. The ten appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education. The Board shall annually elect one of the appointed members to serve as Chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) It shall be the duty of the Board to advise, consult with, and make recommendations to the Secretary on important matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users[, and the Secretary shall include in his annual report to the Congress a statement covering the recommendations made by the Board and the disposition thereof]. The Secretary is authorized to use the services of any member or members of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as he may determine.

(c) Each appointed member of the Board shall hold office for a term of four years, except that (A) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term, and (B) the terms of the members first taking office after the date of enactment of this part shall expire as follows: three at the end of four years after such date, three at the end of three years after such date, two at the end of two years after such date, and two at the end of one year after such date, as designated by the Secretary

at the time of appointment. None of the appointed members shall be eligible for reappointment within one year after the end of his preceding term.

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PART J—ASSISTANCE TO MEDICAL LIBRARIES

DECLARATION OF POLICY, STATEMENT OF PURPOSE, AND AUTHORIZATION OF APPROPRIATIONS

SEC. 390. (a) The Congress hereby finds and declares that (1) the unprecedented expansion of knowledge in the health sciences within the past two decades has brought about a massive growth in the quantity, and major changes in the nature of, biomedical information, materials, and publications; (2) there has not been a corresponding growth in the facilities and techniques necessary adequately to coordinate and disseminate among health scientists and practitioners the ever-increasing volume of knowledge and information which has been developed in the health science field; (3) much as the value of the ever-increasing volume of knowledge and information which has been, and continues to be, developed in the health science field will be lost unless proper measures are taken in the immediate future to develop facilities and techniques necessary to collect, preserve, store, process, retrieve, and facilitate the dissemination and utilization, of such knowledge and information.

(b) It is therefore the policy of this part to—

(1) assist in the training of medical librarians and other information specialists in the health sciences;

(2) assist, through grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists, in the compilation of existing, and the creation of additional, written matter which will facilitate the distribution and utilization of knowledge and information relating to scientific, social, and cultural advancements in sciences related to health;

(3) assist in the conduct of research, investigations, and demonstrations in the field of medical library science and related activities, and in the development of new techniques, systems, and equipment for processing, storing, retrieving, and distributing information in the sciences related to health;

(4) assist in establishing, expanding, and improving the basic resources of medical libraries and related facilities;

(5) assist in the development of a national system of regional medical libraries each of which would have facilities of sufficient depth and scope to supplement the services of other medical libraries within the region served by it, and

(6) provide financial support to biomedical scientific publications.

(c) For the purpose of grants and contracts under sections 393, 394, 395, 396, and 397, there are authorized to be appropriated $17,500,000 for the fiscal year ending June 30, 1975, $20,000,000 for

the fiscal year ending June 30, 1976, $14,600,000 for the fiscal year ending September 30, 1978, $15,000,000 for the fiscal year ending September 30, 1979, $16,500,000 for the fiscal year ending September 30, 1980, $18,500,000 for the fiscal year ending September 30, 1981, [and] $7,500,000 for the fiscal year ending September 30, 1982, *$8,000,000 for the fiscal year ending September 30, 1983, $8,500,000 for the fiscal year ending September 30, 1984, and $9,000,000 for the fiscal year ending September 30, 1985.*

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL CANCER INSTITUTE

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CANCER RESEARCH AND OTHER ACTIVITIES

SEC. 401. (a) In carrying out the purposes of section 301 with respect to cancer, the Secretary, through the Institute and in cooperation with the National Cancer Advisory Board, shall—

(1) conduct, assist, and foster research, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer, *and the continuing care of the cancer patient and the family of the cancer patient;*

(2) promote the coordination of research conducted by the Institute and similar research conducted by other agencies and organizations and by individuals;

(3) provide clinical training and instruction in technical matters relating to the diagnosis and treatment of cancer;

(4) secure for the Institute consultation services and advice of cancer experts from the United States and abroad;

(5) cooperate with State health agencies in the prevention, control, and eradication of cancer; and

(6) procure, use, and lend radium as provided in subsection (b).

(b) In carrying out subsection (a), all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and the Secretary is authorized—

(1) to purchase [radium, from time to time and] *radium* without regard to section 3709 of the Revised Statutes, and to make such radium available for the purposes of this part, both to the Service and by loan to other agencies and institutions for such consideration and subject to such conditions as he may prescribe; and

(2) to provide the necessary facilities where training and instructions may be given in all technical matters relating to the diagnosis and treatment of cancer to persons found by the Secretary to have proper technical qualifications and designated by him for such training or instruction and to fix and pay them a per diem allowance during such training or instruction.

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CANCER CONTROL PROGRAMS

SEC. 403. The Director of the Institute shall establish and support demonstration, *developmental research*, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for *the continuing care of the cancer patient and the family of the cancer patient, including* rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education, *research*, and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting the detection, diagnosis, prevention, and treatment of cancer and [rehabilitation and counseling] *rehabilitation, counseling, and continuing care* respecting cancer to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of health professionals in—

(A) effective methods for the early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

DUTIES AND FUNCTIONS OF THE DIRECTOR

SEC. 404. (a) The Director of the Institute in carrying out the National Cancer Program shall—

[(1) collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country;]

(1) collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the maintenance and operation of the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country;

(2) establish or support the large-scale production or distribution of specialized biological materials and other therapeutic

substances for research and set standards of safety and care for persons using such materials;

(3) support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States;

(4) support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines for investigators, physicians, and allied health professionals for participation in clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards;

(5) expeditiously utilize existing research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise;

(6) encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(7) provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer;

(8) (A) prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including and estimate of the number and type of personnel needs for the National Cancer Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute; [and]

(9) as soon as practicable after the end of each fiscal year, prepare in consultation with the National Cancer Advisory Board and submit to the Secretary, for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress, a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding fiscal year, which shall include a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the Program, and a plan for the Program during the next five years[.]*; and*

(10) advise the National Cancer Advisory Board of the status of any investigation concerning any recipient of a grant or contract from the National Cancer Institute, unless the office or unit of the Institute which is conducting the investigation advises the Director that disclosure to the Board under this paragraph will jeopardize the investigation.

(b) The Director of the Institute (after consultation with the National Cancer Advisory Board) in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act is authorized—

(1) to obtain (in accordance with section 3109 of title 5, United States Code and if authorized by the National Cancer Advisory Board, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary to acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) to appoint, in consultation with the Secretary, one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(5) to accept voluntary and uncompensated services;

(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution;

(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally;

(9) to award grants, in consultation with the Secretary, for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program; and

(10) to call special meetings to the National Cancer Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other actions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

SCIENTIFIC REVIEW

SEC. 405. (a) The Director of the Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Cancer Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act for cancer research or training—

(1) if the direct costs of such research and training do not exceed [$35,000,] *$50,000*, but only after appropriate review for scientific merit, and

(2) if the direct costs of such research and training exceed [$35,000,] *$50,000*, but only after appropriate review for scientific merit and recommendation for approval by the National Cancer Advisory Board under section 407(b)(3).

NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 406. (a) The Director of the Institute is authorized to provide for the establishment of new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into coperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under subsection (a)) for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under section 477), (2) staffing and other basic operating costs, including such patient care costs as are required for research, (3) clinical training (including clinical training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer, and (4) demonstration purposes. The aggregate of payments (other than payments for construction) made to any center in support of such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by

the Bureau of Labor Statistics, in the cost of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed $5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of $5,000,000. As used in this section, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which fellowship support may be provided under section 472. Support of a center under this section may be for a period of not to exceed [three] *five* years and may be extended by the Director of the Institute, *in consultation with the National Cancer Advisory Board*, for additional periods of not more than [three] *five* years each, after review of the operations of such center by an appropriate scientific review group established by the Director of the Institute.

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AUTHORIZATION OF APPROPRIATIONS

SEC. 410. (a) For the purpose of carrying out this part (other than section 403), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1972; $500,000,000 for the fiscal year ending June 30, 1973; $600,000,000 for the fiscal year ending June 30, 1974; $750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; $985,000,000 for the fiscal year ending September 30, 1977; $923,590,000 for the fiscal year ending September 30, 1978; $924,500,000 for the fiscal year ending September 30, 1979; $927,000,000 for the fiscal year ending September 30, 1980; $1,015,700,000 for the fiscal year ending September 30, 1981; [and] $1,109,000,000 for the fiscal year ending September 30, 1982; *$916,801,420 for the fiscal year ending September 30, 1983; $967,225,498 for the fiscal year ending September 30, 1984; and $1,015,586,772 for the fiscal year ending September 30, 1985.*

(b) There are authorized to be appropriated to carry out section 403, $20,000,000 for the fiscal year ending June 30, 1972; $30,000,000 for the fiscal year ending June 30, 1973; $40,000,000 for the fiscal year ending June 30, 1974; $53,500,000 for the fiscal year ending June 30, 1975; $68,500,000 for the fiscal year ending June 30, 1976; $88,500,000 for the fiscal year ending September 30, 1977; $84,560,000 for the fiscal year ending September 30, 1978; $90,500,000 for the fiscal year ending September 30, 1979; $103,000,000 for the fiscal year ending September 30, 1980; $112,900,000 for the fiscal year ending September 30, 1981; [and] $123,200,000 for the fiscal year ending September 30, 1982; *$58,642,380 for the fiscal year ending September 30, 1983; $61,867,710 for the fiscal year ending September 30, 1984; and $64,961,096 for the fiscal year ending September 30, 1985.*

(c) The authority of the Secretary to enter into any contract for the conduct of a program under section 404(a)(7) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

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NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

SEC. 413. (a) The Director of the Institute, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this part referred to as the "Program") to expand, intensify, and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases and blood resources (including its activities under section 412) and shall carry out the Program in accordance with such plan. The Program shall be coordinated with the other research institutes of the National Institutes of Health to the extent that they have responsibilities respecting such diseases and shall provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(2) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(3) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including emergency medical service), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(4) establishment of programs that will focus and apply scientific and technological efforts involving biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of those diseases;

(5) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of prevention, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(6) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionalization, and distribution of it and its products;

(7) the education and training of scientists, clinicians, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(8) public and professional education relating to all aspects of such diseases and the use of blood and blood products and the management of blood resources;

(9) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, [and hemolytic and hemophilic disease] *hemolytic, and hemophilic diseases, and Cooley's anemia*) and for the development and demonstration of diagnostic, treatment, and preventive approaches to these diseases; and

(10) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases, which programs shall include programs for (A) the training of paraprofessionals in (i) emergency treatment procedures, and (ii) utilization and operation of emergency medical equipment, (B) the development and operation of (i) mobile critical care units (including helicopters and other airborne units where appropriate), (ii) radio, telecommunications, and other means of communications, and (iii) electronic monitoring systems, and (C) the coordination with other community services and agencies in the joint use of all forms of emergency vehicles, communications systems, and other appropriate services.

The Program shall give special emphasis to the continued development in the Institute of programs relating to atherosclerosis, hypertension, thrombosis, and congenital abnormalities of the blood vessels as causes of stroke, and to effective coordination of such programs with related stroke programs in the National Institute of Neurological Diseases and Stroke.

(b) (1) The plan required by subsection (a) of this section shall (A) be developed within one hundred and eighty days after the effective date of this section, (B) be transmitted to the Congress, and (C) set out the Institute's staff requirements to carry out the Program and recommendations for appropriations for the Program.

(2) The Director of the Institute shall, as soon as practicable after the end of each fiscal year, prepare in consultation with the Council and submit a report to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress, on the activities, progress, and accomplishments under the Program during the preceding fiscal year and a plan for the Program during the next five years. [Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the Program during such five years.]

(c) In carrying out the Program, the Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultations with the Council and without regard to any other provision of this Act, may—

(1) if authorized by the Council, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hun-

dred experts or consultants who have scientific or professional qualifications;

(2) acquire, construct, improve, repair, operate, alter, renovate, and maintain heart blood vessel, lung, and blood disease and blood resources laboratory, research, training, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years; and

(3) enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution.

(d) There shall be in the Institute an Assistant Director for Prevention, Education, and Control who shall be appointed by the Director of the Institute. The Director of the Institute, acting through the Assistant Director for Prevention, Education, and Control shall conduct a program to provide on a timely basis the public and the health professions with health information with regard to cardiovascular and, blood and pulmonary diseases and blood resources. In the conduct of such program, special emphasis shall be placed upon dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases.

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

SEC. 414. (a) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

(b) There is authorized to be appropriated to carry out this section $25,000,000 for the fiscal year ending June 30, 1973, $35,000,000 for the fiscal year ending June 30, 1974, $45,000,000 for the fiscal year ending June 30, 1975, $10,000,000 for fiscal year 1976, $30,000,000 for the fiscal year ending September 30, 1977, $30,000,000 for the fiscal year ending

September 30, 1978, $40,000,000 for the fiscal year ending September 30, 1979, $45,000,000 for the fiscal year ending September 30, 1980, $49,300,000 for the fiscal year ending September 30, 1981, [and] $53,800,000 for the fiscal year ending September 30, 1982, *$38,100,000 for the fiscal year ending September 30, 1983, $40,258,800 for the fiscal year ending September 30, 1984, and $42,271,740 for the fiscal year ending September 30, 1985.*

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES

SEC. 415. (a)(1) The Director of the Institute may provide for the development of—

(A) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart and blood vessel diseases,

(B) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children), and

(C) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases.

(3) Centers developed under this subsection may be supported under subsection (b) or under any other applicable provision of law. The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council, may enter into cooperative agreements with public or nonprofit private agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for, existing or new centers (including centers established under subsection (a)) for basic or clinical research into, training in, and demonstration of, the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases. Funds paid to centers under cooperative agreements under this subsection may be used for—

(1) construction, notwithstanding section 477,

(2) staffing and other basic operating costs, including such patient care as are required for research,

(3) training, including training for allied health professions personnel, and

(4) demonstration purposes.

The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by the Bureau of Labor Statistics, in the costs of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed $5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of $5,000,000. Support of a center under this subsection may be for a period of not to exceed five years and may be extended by the Director of the Institute, *in consultation with the National Heart, Lung, and Blood Advisory Council*, for additional periods of not more than five years each, after review of the operations of such center by an appropriate scientific review group established by the Director. As used in this section, the term "construction" does not include the acquisition of land; and the term "training" does not include research training for which fellowship support may be provided under section 472.

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ADMINISTRATION

SEC. 419A. (a) In carrying out the provisions of section 412 all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and except as provided in subsection (c), grants-in-aid for heart, blood vessel, lung, and blood disease research and training projects and projects with respect to the use of blood and blood products and the management of blood resources shall be made only after review and recommendation of the Council.

(b) The Secretary may, in accordance with section 501, accept conditional gifts for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases and into the use of blood and blood

products and the management of blood resources, or for the acquisition of grounds or for the erection, equipment, or maintenance of premises, buildings or equipment of the Institute. Donations of $50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Heart, Lung, and Blood Institute may approve grants under this Act for research and training in heart, blood vessel, lung, and blood diseases and for research and training in the use of blood and blood products and the management of blood resources—

(1) if the direct costs of such research and training do not exceed [$35,000] *$50,000*, but only after appropriate review for scientific merit but without review and recommendation by the Council, and

(2) if the direct costs of such research and training exceed [$35,000] *$50,000*, but only after appropriate review for scientific merit and recommendation for approval by the Council.

AUTHORIZATION OF APPROPRIATIONS

SEC. 419B. For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated $375,000,000 for the fiscal year ending June 30, 1973, $425,000,000 for the fiscal year ending June 30, 1974, $475,000,000 for the fiscal year ending June 30, 1975, $339,000,000 for fiscal year 1976, $373,000,000 for the fiscal year ending September 30, 1977, $426,320,000 for the fiscal year ending September 30, 1978, $470,000,000 for the fiscal year ending September 30, 1979, $515,000,000 for the fiscal year ending September 30, 1980, $564,300,000 for the fiscal year ending September 30, 1981, [and] $616,100,000 for the fiscal year ending September 30, 1982, *$525,614,780 for the fiscal year ending September 30, 1983, $554,523,592 for the fiscal year ending September 30, 1984, and $582,449,772 for the fiscal year ending September 30, 1985.*

Of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums shall be reserved for programs under this part respecting diseases of the lung and not less than 15 per centum of such sums shall be reserved for programs under this part for programs respecting blood diseases and blood resources.

PART C—NATIONAL INSTITUTE OF DENTAL RESEARCH

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DENTAL DISEASE RESEARCH AND TRAINING

SEC. 422. In carrying out the purposes of section 301 with respect to dental diseases and conditions the [Surgeon General] *Secretary*, through the Institute and in cooperation with the National Advisory Dental Research Council (hereafter in this part referred to as the "Council") shall—

(a) conduct, assist, and foster researches, investigations, experiments, and studies relating to the cause, prevention, and

methods of diagnosis and treatment of dental diseases and conditions;

(b) promote the coordination of researches conducted by the Institute, and similar researches conducted by other agencies, organizations, and individuals;

(c) secure for the Institute consultation services and advice of persons from the United States or abroad who are experts in the field of dental diseases and conditions;

(d) cooperate with State health agencies in the prevention and control of dental diseases and conditions; and

(e) provide clinical training and instruction and establish and maintain clinical traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of dental diseases and conditions with such stipends and allowances (including travel and subsistence expenses) for trainees as he may deem necessary, the number of persons receiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and, in addition, provide for such training, instruction, and traineeships through grants, upon recommendations of the Council, to public and other nonprofit institutions.

ADMINISTRATION

SEC. 423. (a) In carrying out the provisions of section 422 all appropriate provisions of section 301 shall be applicable to the authority of the [Surgeon General] *Secretary*, and grants-in-aid for dental research and training projects shall be made only after review and recommendation of the Council made pursuant to section 424.

(b) The Surgeon General shall recommend to the Secretary acceptance of conditional gifts, pursuant to section 501, for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions, or for the acquisition of grounds or for the erection, equipment, or maintenance of premises, buildings, or equipment of the Institute. Donations of $50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

FUNCTIONS OF THE COUNCIL

SEC. 424. The Council is authorized to—

(a) review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis and treatment of dental diseases and conditions, and certify approval to the [Surgeon General] *Secretary* for prosecution under section 422(a) hereof, of any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of dental diseases and conditions;

(b) collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of dental diseases

and conditions, by correspondence or by personal investigation of such studies, and with the approval of the [Surgeon General] *Secretary* make available such information through appropriate publications for the benefit of health agencies and organizations (public or private), physicians, dentists, or any other scientists, and for the information of the general public;

(c) review applications from any university, hospital, laboratory, or other institution, whether public or private, or from individuals, for grants-in-aid for research projects relating to dental diseases and conditions, and certify to the [Surgeon General] *Secretary* its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions;

(d) recommend to the [Surgeon General] *Secretary* for acceptance conditional gifts pursuant to section 501 for carrying out the purposes of this part;

(e) make recommendations to the [Surgeon General] *Secretary* with respect to carrying out the provisions of this part; and

(f) review applications from any public or other nonprofit institution for grants-in-aid for training, instruction, and traineeships in matters relating to the diagnosis, prevention, and treatment of dental diseases and conditions, and certify to the [Surgeon General] *Secretary* its approval of such applications for grants-in-aid as it determines will best carry out the purposes of this Act.

PART D—NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE, AND OTHER INSTITUTES

ESTABLISHMENT OF INSTITUTES

SEC. 431. (a) The [Surgeon General] *Secretary* shall establish in the Public Health Service an institute for research on arthritis, rheumatism, and metabolic diseases and an institute for research on neurological diseases (including epilepsy, cerebral palsy, and multiple sclerosis) and blindness, and he shall also establish a national advisory council or committee for each such institute to advise, consult with, and make recomendations to him with respect to the activities of the institute with which each council or committee is concerned.

(b) The [Surgeon General is authorized with the approval of the Secretary to] *Secretary shall* establish in the Public Health Service one or more additional institutes to conduct and support scientific research and professional training relating to the cause, prevention, and methods of diagnosis and treatment of other particular diseases or groups of diseases (including poliomyelitis and leprosy) whenever the [Surgeon General] *Secretary* determines that such action is necessary to effectuate fully the purposes of section 301 with respect to such disease or diseases. Any institute established pursuant to this subsection may in like manner be abolished and its functions transferred elsewhere in the Public Health Service upon a finding by the [Surgeon

General] *Secretary* that a separate institute is no longer required for such purposes. In lieu of the establishment pursuant to this subsection of an additional institute with respect to any disease or diseases, the [Surgeon General] *Secretary* may expand the functions of any institute established under subsection (a) of this section or under any other provision of this Act so as to include functions with respect to such disease or diseases and to terminate such expansion and transfer the functions given such institute elsewhere in the Service upon a finding by the [Surgeon General] *Secretary* that such expansion is no longer necessary. In the case of any such expansion of an existing institute, the [Surgeon General] *Secretary* may change the title thereof so as to reflect its new functions.

ESTABLISHMENT OF NATIONAL ADVISORY COUNCILS

SEC. 432. (a) The [Surgeon General is also authorized with the approval of the Secretary] *Secretary is authorized* to establish additional national advisory councils or committees to advise, consult with, and make recommendations to the [Surgeon General] *Secretary* on matters relating to the activities of any institute established under subsection (b) of section 431, or relating to the conduct and support of research and training in such disease or group of diseases (except a disease or group of diseases for which an institute is established under any provision of this title other than section 431(b)) as he may designate. Any such council, and each of the two councils or committees established under section 431(a), shall consist of the [Surgeon General,] *Secretary*, who shall be chairman, the chief medical officer of the Veterans' Administration or his representative and a medical officer designated by the Secretary of Defense, who shall be ex officio members, and of twelve members appointed without regard to the civil service laws by the [Surgeon General with the approval of the] Secretary. The twelve appointed members shall be leaders in the field of fundamental sciences, medical sciences, education, or public affairs, and six of such twelve shall be selected from leading medical or scientific authorities who are outstanding in the study, diagnosis, or treatment of the disease or diseases to which the activities of the institute are directed. Each appointed member of the council shall hold office for a term of four years except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term and except that, of the members first appointed, three shall hold office for a term of three years, three shall hold office for a term of two years, and three shall hold office for a term of one year, as designated by the [Surgeon General] *Secretary* at the time of appointment. None of such twelve members shall be eligible for reappointment until a year has elapsed since the end of his preceding term.

(b) In lieu of appointment of an additional advisory council or committee upon the establishment pursuant to subsection (b) of section 431 of an additional institute or upon expansion pursuant to such subsection of the functions of an institute, the [Surgeon General] *Secretary* may expand the functions of an advisory council or committee, established under section 431(a) of any other provisions of this Act so

as to include functions with respect to the particular disease or diseases to which the activities of the additional institute or the expanded activities of the existing institute are directed. In the case of any such expansion of an existing council or committee, the membership thereof representing persons outstanding in activities with which the council or committee is concerned may be changed or increased so as to include some persons outstanding in the new activities. Any new council or committee established under subsection (a) of this section or any expansion of an existing council or committee under this subsection may be terminated by the [Surgeon General] *Secretary* at, before, or after the termination of the new institute or expansion of the existing institute which occasioned such new council or committee or expansion of an existing council or committee. In the case of any such expansion of an existing council or committee, the [Surgeon General] *Secretary* may change the title thereof so as to reflect its new functions.

FUNCTIONS

SEC. 433. (a) Where an institute has been established under this part, the [Surgeon General] *Secretary* shall carry out the purposes of section 301 with respect to the conduct and support of research relating to the disease or diseases to which the activities of the institute are directed, through such institute and in cooperation with the national advisory council or committee established or expanded by reason of the establishment of such institute. The provisions of this subsection shall also be applicable to any institute established by any other provision of this Act to the extent that such institute does not already have the authority conferred by this subsection.

(b) Upon the appointment of a national advisory council or committee for an institute established under this part or the expansion of an existing institute pursuant to this part, such council or committee shall assume the duties, functions, and powers of the National Advisory Health Council with respect to grants-in-aid for research and training projects relating to the disease or diseases to which the activities of the institute are directed.

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[DIABETES, ARTHRITIS, AND DIGESTIVE DISEASES ADVISORY BOARDS]

DIABETES, ARTHRITIS, KIDNEY AND UROLOGIC DISEASES, AND DIGESTIVE DISEASES ADVISORY BOARDS

SEC. 437. (a) The Secretary shall establish the National Arthritis Advisory Board, the National Diabetes Advisory Board, *the National Kidney and Urologic Diseases Advisory Board*, and the National Digestive Diseases Advisory Board (hereinafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting, ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent

the specialities and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who suffers from the disease and one member who is a parent of a person who suffers from the disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of each Advisory Board: The Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, the Director of the Center for Disease Control, the chief medical director of the Veterans' Administration, a medical officer designated by the Department of Defense (or the designees of such ex officio members), the Associate Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases for the diseases for which the Board is established, and such other officers and employees of the United States as the Secretary deems necessary for the Advisory Board to carry out its functions. In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, the Administrator of the Health Resources Administration, and the Administrator of the Health Services Administration (or their designees of such ex officio members).

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of an Advisory Board is three years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than ninety days from the date the vacancy occurs. In the case of the National Diabetes Advisory Board and the National Arthritis Advisory Board, six of the members of each such Advisory Board whose terms expired on September 30, 1980, shall be reappointed for a term of three years.

(e) The members of each Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the National Institute for Arthritis, Diabetes, and Digestive and Kidney Diseases, but not less often than four times a year.

(h) Each Advisory Board shall—

(1) review and evaluate the implementation of the plan referred to in section 434(e) regarding the diseases with respect to which the Advisory Board was established;

(2) periodically update the plan referred to in paragraph (1) to ensure its continuing relevance;

(3) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to Congress, the Secretary, the Director of the National Institutes of Health, the Director of the National Institute for Arthritis, Diabetes, and Digestive and Kidney Diseases, and the heads of other appropriate Federal agencies for the implementation of such plan; and

(4) maintain liaison with other advisory bodies related to Federal agencies involved in the imaplementation of such plan, the Coordinating Committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcomittees. The subcomittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Each Advisory Board shall submit to the Secretary and Congress an annual report which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made during such year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in the fiscal year for which the report is made; and

(4) contains the Advisory Board's recommendations, if any, for changes in the plan referred to in subsection (h)(1).

(k) For each Advisory Board there is authorized to be appropriated $300,000 for the fiscal year ending September 30, 1981; $300,000 for the fiscal year ending September 30, 1982; and $300,000 for the fiscal year ending September 30, 1983.

(l) Each Advisory Board shall expire on September 30, [1983] *1985*.

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PART E—INSTITUTES OF CHILD HEALTH AND HUMAN DEVELOPMENT AND OF GENERAL MEDICAL SCIENCES

ESTABLISHMENT OF INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

SEC. 441. (a) The [Surgeon General is authorized, with the approval of the Secretary,] *Secretary is authorized* to establish in the Public Health Service the National Institute of Child Health and Human Development for the conduct and support of research and training relating to maternal health, child health, and human development, including research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the process of human growth and development, including prenatal development.

(b) The Secretary shall carry out through the National Institute of Child Health and Human Development the purposes of section 301 with respect to the conduct and support of research which specifically relates to sudden infant death syndrome.

ESTABLISHMENT OF INSTITUTE OF GENERAL MEDICAL SCIENCES

SEC. 442. The [Surgeon General is authorized, with the approval of the Secretary,] *Secretary is authorized* to establish in the Public Health Service an institute for the conduct and support of research and training in the general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other institutes, or are outside the general area of responsibility of any other institute, established under or by this Act.

ESTABLISHMENT OF ADVISORY COUNCILS

SEC. 443. (a) The [Surgeon General is authorized, with the approval of the Secretary,] *Secretary is authorized* to establish an advisory council or committee to advise, consult with, and make recommendations to the [Surgeon General] *Secretary* on matters relating to the activities of the institute established under section 441. He may also, with such approval, establish such a council or committee with respect to the activities of the institute established under section 442.

(b) The provisions relating to the composition, terms of office of members, and reappointment of members of advisory councils or committees under section 432(a) shall be applicable to any council or committee established under this section, except that, in lieu of the requirement in such section that six of the members be outstanding in the study, diagnosis, or treatment of a disease or diseases, six of such members shall be elected from leading medical or scientific authorities

who are outstanding in the field of research or training with respect to which the council or committee is being established, and except that the [Surgeon General with the approval of the Secretary,] *Secretary* may include on any such council or committee established under this section such additional ex officio members as he deems necessary in the light of the functions of the institute with respect to which it is established.

(c) Under appointment of any such council or committee, it shall assume all or such part as the [Surgeon General may, with the approval of the Secretary,] *Secretary may* specify of the duties, functions, and powers of the National Advisory Health Council relating to the research or training projects with which such council or committee established under this part is concerned and such portion as the [Surgeon General] *Secretary* may specify (with such approval) of the duties, functions, and powers of any other advisory council or committee established under this Act relating to such projects.

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PRESERVATION OF EXISTING AUTHORITY

SEC. 445. Nothing in this part shall be construed as affecting the authority of the Secretary under section 2 of the Act of April 9, 1912 (42 U.S.C. 192), or title V of the Social Security Act (42 U.S.C., ch. 7, subch. V), or as affecting the authority of the [Surgeon General] *Secretary* to utilize institutes established under other provisions of this Act for research or training activities relating to maternal health, child health, and human development or to the general medical sciences and related sciences

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PART H—NATIONAL INSTITUTE ON AGING

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FUNCTIONS

SEC. 463. (a) The Secretary (1) shall, through the Institute, carry out the purposes of section 301 with respect to research investigations, experiments, demonstrations, and studies related to the aging process and the diseases and other special problems and needs of the aged, except that the Secretary shall determine the area in which and the extent to which he will carry out such activities in furtherance of the purposes of section 301 through the Institute or another institute established by or under other provisions of this Act, or both of them, when both such institutes have functions with respect to the same subject matter and (2) shall be responsible for coordinating such activities so as to avoid unproductive and unnecessary overlap and duplication of such functions. The Secretary may also provide training and instruction and establish traineeships and fellowships, in the Institute and elsewhere, in matters relating to study and investigation of the aging process and the diseases and other special problems and needs of the aged. The Secretary may provide trainees and fellows participating in such training and instruction or in such traineeships and fellowships with such

stipends and allowances (including travel and subsistence expenses and dependency allowances) as he deems necessary, and, in addition, provide for such training, instruction, traineeships, fellowships through grants to public or other nonprofit institutions. In carrying out his health manpower training responsibilities under this Act or any other Act, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) The Secretary shall, through the Institute, conduct scientific studies to measure the impact on the biological, medical, and psychological aspects of aging of all programs and activities assisted or conducted by the Department of [Health, Education, and Welfare] *Health and Human Services.*

(c) The Secretary, through the Institute, shall carry out public information and education programs designed to disseminate as widely as possible the findings of Institute-sponsored and other relevant aging research and studies and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

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PART I—GENERAL PROVISIONS

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NATIONAL RESEARCH SERVICE AWARDS

SEC. 472. (a) (1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration or under programs administered by the Division of Nursing of the Health Resources Administration, in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the Institute and Administration or Division of Nursing are directed,

(ii) training at the Institutes and Administration of individuals to undertake such research,

(iii) biomedical and behavioral research at public institutions and at nonprofit private institutions, and

(iv) pre- and post-doctoral training at such public and private institutions of individuals to undertake biomedical and behavioral research; and

(B) make grants to public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake biomedical and behavioral research and the research described in subparagraph (A) (iv)) in the matters described in subparagraph (A) (i).

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be

considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be.

(2) National Research Service Awards may not be used to support residencies.

(3) In awarding the National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(b)(1) No national Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c)(1); and

(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the Award will be conducted.

An application for an Award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section other than paragraph (1) of this subsection, National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for predoctoral training, and

(B) three years in the aggregate for postdoctoral training,

unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living for the recipients of the Awards as the Seecretary may deem necessary. A National Research Service Award made to an individual for research of research training at a non-Federal public or nonprofit private institu-

tion shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

[(c) (1) Each individual who is awarded a National Research Service Award (other than an individual who is a prebaccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

[(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment.

[(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's Award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

[(4) (A) If any individual to whom the requirement of paragaraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A=\phi(t-s/t)$$

in which "A" is the amount the United States is entitled to recover; "ϕ" is the sum of the total amount paid under one or more National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by him in accordance with paragraphs (1) and (2) of this subsection.

[(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

[(5)(A) Any obligation of any individual under paragraph (3) shall be canceled upon the death of such individual.

[(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual and if enforcement of such obligation with respect to any individual would be against equity and good conscience.]

[(d)](C) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such Awards $207,947,000 for this fiscal year ending June 30, 1975, $165.000,000 for fiscal year 1976, $185,000,000 for the fiscal year ending September 30, 1977, $161,390,000 for the fiscal year ending September 30, 1978, $197,500,000 for the fiscal year ending September 30, 1979, $210,000,000 for the fiscal year ending September 30, 1980, $222,500,00 for the fiscal year ending September 30, 1981, $182,000,000 for the fiscal year ending September 30, 1982, and $195,000,000 for the fiscal year ending September 30, 1983. Of the sums appropriated under this subsection, not less than 15 per centum shall be made available for payments under National Research Service awards provided by the Secretary under subsection (a)(1)(A) and not less than 50 per centum shall be made avilable for grants under subsection (a)(1)(B) for National Research Service Awards. In any fiscal year not more than 4 per centum of the amount obligated to be expended under this section may be obligated for National Research Service Awards for periods of three months or less.

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PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS

SEC. 475. (a) The Secretary, after consultation with the Director of the National Institutes of Health, and where appropriate, the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and the head of the Division of Nursing of the Health Resources Administration (or the successor to either such entity), shall by regulation require appropriate scientific peer review of—

(1) applications made after the effective date of such regulations for grants under this Act for biomedical and behavioral research (including research under programs of such Division of Nursing); and

(2) biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title, the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, or the Division of Nursing of the Health Resources Administration (or the successor to either such entity).

(b) Regulations promulgated under subsection (as) shall, to the extent practical, require that the review of grant applications required by the regulations be conducted—

(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to

applications for grants under this Act for biomedical and behavioral research, and

(2) by peer review groups performing such review on or before such date.

(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.

(d) By January 1, 1983, and annually thereafter, the Secretary shall prepare and transmit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning any activities undertaken in the preceding fiscal year to improve the grant, contracting, accountability, and peer review procedures of the National Institutes of Health (including the National Cancer Institute).

REPORT ON PREVENTIVE MEDICINE AND HEALTH PROMOTION

SEC. 480. By January 1, 1984, and annually thereafter, the Secretary shall prepare and transmit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning all activities of the National Institutes of Health during the preceding fiscal year relating to preventive medicine and health promotion, including the number and type of personnel involved in such activities.

INVESTIGATIONS

SEC. 481. The Director of each Research Institute in the National Institutes of Health shall notify the Advisory Board of such Research Institute of the status of any investigation concerning any recipient of a grant or contract from such Research Institute, unless the office or unit of the Research Institute or of the National Institutes of Health which is conducting the investigation advises the Director that disclosure to the Board under this section will jeopardize the investigation.

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TITLE VII—HEALTH RESEARCH AND TEACHING FACILITIES AND TRAINING OF PROFESSIONAL HEALTH PERSONNEL

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PART C—STUDENT ASSISTANCE

Subpart I—Federal Program of Insured Loans to Graduate Students in Health Professions Schools

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DEFINITIONS

SEC. 737. As used in this subpart:

(1) The term "eligible institution" means, with respect to a fiscal year, a school of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, pharmacy, public health or chiropractic, or a graduate program in health administration or clinical psychology.

(2) The term "school of chiropractic" means a school *in a State* which provides training leading to a degree of doctor of chiropractic or an equivalent degree and which is accredited in the manner described in section 701(5).

(3) The term "graduate program in clinical psychology" means a graduate program in a public or nonprofit private institution in a State which provides training leading to a doctoral degree in clinical psychology or an equivalent degree and which is accredited in the manner described in section 701(5).

(4) The term "eligible lender" means an eligible institution, an agency or instrumentality of a State, a financial or credit institution (including an insurance company) which is subject to examination and supervision by an agency of the United States or of any State, or a pension fund approved by the Secretary for this purpose.

(5) The term "line of credit" means an arrangement or agreement between the lender and the borrower whereby a loan is paid out by the lender to the borrower in annual installments, or whereby the lender agrees to make, in addition to the initial loan, additional loans in subsequent years.

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PART F—GRANTS AND CONTRACTS FOR PROGRAMS AND PROJECTS

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AREA HEALTH EDUCATION CENTERS

SEC. 781. (a)(1) The Secretary shall enter into contracts with schools of medicine and osteopathy for the planning, development, and operation of area health education center programs.

(2) The Secretary shall enter into contracts with schools of medicine and osteopathy, which have previously received Federal financial assistance for an area health education center program under section 802 of the Health Professionals Educationals Assistance Act of 1976 in fiscal year 1979, or under this secstion to carry out [under area health education center programs]—

(A) projects to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system;

(B) projects to encourage the regionalization of educational responsibilities of the health professions schools; and

(C) projects designed to prepare, through preceptorships and other programs, individuals subject to a service obligation under

the National Health Service Corps scholarship program to effectively provide health services in health manpower shortage areas.

(b) An area health education center program shall be a cooperative program of one or more medical or osteopathic schools and one or more nonprofit private or public area health education centers.

(c) Each medical or osteopathic school participating in an area health education center program shall—

(1) provide for the active participation in such program by individuals who are associated with the administration of the school and each of the departments (or specialties if the school has no such departments) of internal medicine, pediatrics, obstetrics and gynecology, surgery, psychiatry, and family medicine;

(2) provide that no less than 10 percent of all undergraduate medical or osteopathic clinical education of the school will be conducted in an area health education center and at locations under the sponsorship of such center;

(3) be responsible for, or conduct, a program for the training of physician assistants (as defined in section 701(7)) or nurse practitioners (as defined in section 822) which gives special consideration to the enrollment of individuals from, or intending to practice in, the area served by the area health education center of the program; and

(4) provide for the active participation of at least 2 schools or programs of other health professions (including a school of dentistry if there is one affiliated with the university with which the school of medicine or osteopathy is affiliated) in the educational program conducted in the area served by the area health education center.

The requirement of paragraph (3) shall not apply to a medical or osteopathic school participating in an area health education center program if another such school participating in the same program meets the requirement of that paragraph. The Secretary may waive, for good cause shown, all or part of the requirement of paragraph (2) as it applies to a medical or osteopathic school participating in an area health education center program if another such school participating in the same program meets the requirement of that paragraph.

(d)(1) Each area health education center shall specifically designate a geographic area in which it will serve, or shall specifically designate a medically underserved population it will serve (such area or population with respect to such center in this section referred to as "the area served by the center"), which area or population is in a location remote from the main site of the teaching facilities of the school or schools which participate in the program with such center.

(2) Each area health education center shall—

(A) provide for or conduct training in health education services, including education in nutrition evaluation and counseling, in the area served by the center;

(B) assess the health manpower needs of the area served by the center and assist in the planning and development of training programs to meet such needs;

(C) provide for or conduct a rotating osteopathic internship or a medical residency training program in family medicine, general

internal medicine, or general pediatrics in which no fewer than six individuals are enrolled in first-year positions in such program;

(D) provide opportunities for continuing medical education (including education in disease prevention) to all physicians and other health professionals (including allied health personnel) practicing within the area served by the center;

(E) provide continuing medical education and other educational support services to the National Health Service Corps members serving within the area served by the center;

(F) encourage the utilization of nurse practitioners and physician assistants within the area served by the center and the recruitment of individuals for training in such professions at the participating medical or osteopathic schools;

(G) arrange and support educational opportunities for medical and other students at health facilities, ambulatory care centers, and health agencies throughout the area served by the center; and

(H) have an advisory board of which at least 75 percent of the members shall be individuals, including both health service providers and consumers, from the area served by the center.

Any area health education center which is participating in as area health education center program in which another center has a medical residency training program described in subparagraph (C) need not provide for or conduct such a medical residency training program.

(e) In entering into contracts under this section the Secretary shall assure that—

(1) at least 75 percent of the total funds provided to any school shall be expended by an area health education center program in the area health education centers;

(2) not more than 75 percent of the total operating funds of a program in any year shall be provided by the Secretary; and

(3) no contract shall provide funds solely for the planning or development of such a program for a period of longer than two years.

The Secretary may vest in entities which have received contracts under section 802 of the Health Professions Educational Assistance Act of 1976, section 744 as in effect before October 1, 1977, or under subsection (a) of this section for area health education centers programs title to any property acquired on behalf of the United States by that entity (or furnished to that entity by the United States) under that contract.

(f) For the purposes of this section the term "area health education center program" means a program which is organized as provided in subsection (b) and under which the participating medical and osteopathic schools and the area health education centers meet the requirements of subsections (c) and (d). The Secretary shall, by regulation, establish standards and criteria for the requirements of this section.

(g) There are authorized to be appropriated to carry out the provisions of this section $20,000,000 for the fiscal year ending September 30, 1978, $30,000,000 for the fiscal year ending September 30, 1979, $40,000,000 for the fiscal year ending September 30, 1980, $21,000,000

for the fiscal year ending September 30, 1982, $22,500,000 for the fiscal year ending September 30, 1983, and $24,000,000 for the fiscal year ending September 30, 1984. The Secretary may obligate not more than 10 percent of the amount appropriated under this subsection for any fiscal year for contracts under subsection (a)(2).

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PART G—PROGRAMS FOR PERSONNEL IN HEALTH ADMINISTRATION AND IN ALLIED HEALTH

Subpart I—Public Health Personnel

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TRAINEESHIPS FOR STUDENTS IN OTHER GRADUATE PROGRAMS

SEC. 791A. (a) The Secretary may make grants to public or nonprofit private educational entities, including graduate schools of social work but excluding accredited schools of public health, which offer a program in health administration, hospital administration, or health policy analysis and planning, which program is accredited by a body or bodies approved for such purpose by the Commissioner of Education and which meets such other quality standards as the Secretary by regulation may prescribe, for traineeships to train students enrolled in such a program.

(b)(1) No grant for traineeships may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such application shall be in such form, be submitted in such manner, and contain such information, as the Secretary by regulation may prescribe. Traineeships under such a grant shall be awarded in accordance with such regulations as the Secretary shall prescribe. The amount of any such grant shall be determined by the Secretary.

(2) Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(3) In awarding traineeships under this section, each applicant shall assure to the satisfaction of the Secretary that at least 80 percent of the funds received under this section shall go to individuals who (A) have previously received a [postbaccalaureate] *baccalaureate* degree, or (B) have three years of work experience in health services.

(c) For payments under grants under subsection (a), there are authorized to be appropriated $2,500,000 for the fiscal year ending September 30, 1978; $2,500,000 for the fiscal year ending September 30, 1979; $2,500,000 for the fiscal year ending September 30, 1980; and $500,000 for the fiscal year ending September 30, 1982, and the next two fiscal years.

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TITLE VIII—NURSE TRAINING

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PART B—ASSISTANCE TO NURSING STUDENTS

Subpart I—Traineeships

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TRAINEESHIPS FOR TRAINING OF NURSE ANESTHETISTS

SEC. 831. (a) (1) The Secretary may make grants to public or private nonprofit institutions to cover the costs of traineeships for the training, in programs which meet such requirements as the Secretary shall by regulation prescribe and which are accredited by an entity or entities designated by the Commissioner of Education, of licensed, registered nurses to be nurse anesthetists.

(2) Payments to institutions under this subsection may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary. Such payments may be used only for traineeships and shall be limited to such amounts as the Secretary finds necessary to cover the costs of tuition and fees, and a stipend and allowances (including travel and subsistence expenses) for the trainees.

(b) For the purpose of making grants under subsection (a), there are authorized to be appropriated $2,000,000 for the fiscal year ending September 30, 1980, *$400,000 for the fiscal year ending September 30, 1983, and $800,000 for the fiscal year ending September 30, 1984.*

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TITLE XV—NATIONAL HEALTH PLANNING AND DEVELOPMENT

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PART C—STATE HEALTH PLANNING AND DEVELOPMENT

DESIGNATION OF STATE HEALTH PLANNING AND DEVELOPMENT AGENCIES

SEC. 1521. (a) For the purpose of the performance within each State of the health planning and development functions prescribed by section 1523, the Secretary shall enter into and renew agreements (described in subsection (b)) for the designation of a State health planning and development agency for each State.

(b) (1) A designation agreement under subsection (a) is an agreement with the Governor of a State for the designation of an agency (selected by the Governor) of the government of that State as the State health planning and development agency (hereinafter in this title referred to as the "State Agency") to administer the State administrative program prescribed by section 1522 and to carry out the State's health planning and development functions prescribed by section 1523. The Secretary may not enter into such an agreement with the Governor of a State unless—

(A) there has been submitted by the State a State administrative program which has been approved by the Secretary,

(B) an application has been made to the Secretary for such an agreement and the application contains assurances satisfactory to the Secretary that the agency selected by the Governor for designation as the State Agency has the authority and resources to administer the State administrative program of the State and to carry out the health planning and development functions prescribed by section 1523, and

(C) in the case of an agreement entered into under paragraph (3), there has been established for the State a Statewide Health Coordinating Council meeting the requirements of section 1524.

(2)(A) The agreement entered into with a Governor of a State under subsection (a) may provide for the designation of a State Agency on a conditional basis with a view to determining the capacity of the designated State Agency to administer the State administrative program of the State and to carry out the health planning and development functions prescribed by section 1523. The Secretary shall require as a condition to the entering into of such an agreement that the Governor submit on behalf of the agency to be designated a plan for the agency's orderly assumption and implementation of such functions.

(B) The period of an agreement described in subparagraph (A) shall not extend beyond the period set forth in [subsection (d)(1)(3)] *subsection (d)*. During such period the Secretary may require that the designated State Agency perform only such of the functions of a State Agency prescribed by section 1523 as he determines it is capable of performing. The number and type of such functions shall, during such period, be progressively increased as the designated State Agency becomes capable of added responsibility, so that by the end of such period the designated State Agency may be considered for designation under paragraph (3).

(C) Any agreement with a Governor of a State entered into under subparagraph (A) may be terminated by the Governor upon ninety days' notice to the Secretary or by the Secretary upon ninety days' notice to the Governor.

(3)(A) If, on the basis of an application for designation as a State Agency (and, in the case of an agency conditionally designated under paragraph (2), on the basis of its performance under an agreement with a Governor of a State entered into under such paragraph), the Secretary determines that the agency is capable of fulfilling, in a satisfactory manner, the responsibilities of a State Agency, he shall enter into an agreement with the Governor of the State designating the agency as the State Agency for the State. No such agreement may be made unless an application therefor is submitted to, and approved by, the Secretary. Any such agreement shall be for a term of not to exceed thirty-six months, except that, prior to the expiration of such term, such agreement may be terminated—

(i) by the Governor at such time and upon such notice to the Secretary as he may by regulation prescribe, or

(ii) by the Secretary if the Secretary determines, in accordance with subparagraph (B), that the designated State Agency is not complying with the provisions of such agreement.

An agreement under this paragraph shall contain such provisions as the Secretary may require to assure that the requirements of this part respecting State Agencies are complied with.

(B) Before the Secretary may terminate an agreement with a designated State Agency under subparagraph (A)(ii), the Secretary shall—

(i) consult with the Statewide Health Coordinating Council of the State for which the State Agency is designated respecting the proposed termination.

(ii) give the State Agency notice of the intention to terminate the agreement and in the notice specify with particularity (I) the basis for the determination of the Secretary that the State Agency is not in compliance with the agreement, and (II) the actions that the State Agency should take to come into compliance with the agreement, and

(iii) provide the State Agency with a reasonable opportunity for a hearing, before an officer or employee of the Department of Health, Education, and Welfare designated for such purpose, on the matter specified in the notice.

The Secretary may not terminate such an agreement before consulting with the National Council on Health Planning and Development respecting the proposed termination. Before the Secretary may permit the term of an agreement to expire without renewing the agreement, the Secretary shall make the consultations prescribed by clause (i) and the preceding sentence, give the State Agency with which the agreement was made notice of the intention not to renew the agreement and the reasons for not renewing the agreement, and provide, as prescribed by clause (iii), the State Agency an opportunity for a hearing on the matter specified in the notice.

(4)(A) An agreement entered into under paragraph (3) for the designation of a State Agency may be renewed by the Secretary for a period not to exceed thirty-six months if upon a review under section 1535 of the State Agency's operation and performance of its function he determines that it has fulfilled, in a satisfactory manner, the responsibilities of a State Agency during the period of the agreement to be renewed and if the applicable State administrative program continues to meet the requirements of section 1522. Before renewing an agreement under this paragraph with a State Agency for a State, the Secretary shall provide each health systems agency designated for a health service area located (in whole or in part) in such State and the Statewide Health Coordinating Council of such State an opportunity to comment on the performance of the State Agency and to provide a recommendation on whether such agreement should be renewed.

(B) If upon a review under section 1535 of the State Agency's operation and performance of its function, the Secretary determines that it has not fulfilled, in a satisfactory manner, the responsibilities of a State Agency during the period of the agreement to be renewed or if the applicable State administrative program does not continue to meet the requirements of section 1522, he may terminate such agreement or return the State Agency to a conditionally designated status under paragraph (2) of subsection (b) for a period not to exceed twelve months. At the end of such period, the Secretary shall either terminate

its agreement with such State Agency or enter into an agreement with such State Agency under paragraph (3) of subsection (b). The Secretary may not terminate an agreement or return a State Agency to a conditionally designated status unless the Secretary has—

(i) provided the State Agency with notice of his intent to return it to a conditional status or terminate the agreement with it and included in that notice specification of any functions which the Secretary has determined the State Agency did not satisfactorily fulfill and of any requirements which the Secretary has determined it has not met;

(ii) provided the State Agency with a reasonable opportunity for a hearing, before an officer or employee of the Department of Health, Education, and Welfare designated for such purpose, on the action proposed to be taken by the Secretary; and

(iii) in the case of a proposed termination, consulted with the National Council on Health Planning and Development respecting the termination.

(c) If a designation agreement with the Governor of a State entered into under subsection (b)(2) or (b)(3) is terminated before the date prescribed for its expiration, the Secretary shall, upon application and in accordance with subsection (b)(2) or (b)(3) (as the Secretary determines appropriate), enter into another agreement with the Governor for the designation of a State Agency.

(d)[1] If an agreement under subsection (b)(3) for the designation of a State Agency for a State is not in effect upon the expiration of—

(A) the fourth fiscal year which begins after the calendar year in which the National Health Planning and Resources Development Act of 1974 is enacted; or

(B)(i) if the legislature of the State is in a regular session on the date of the enactment of the Health Programs Extension Act of 1980 and the legislature will be in session for at least twelve months from such date, [twenty-four months] *forty-two months* from such date, or

(ii) if the legislature of the State is in session on such date of enactment but twelve months do not remain in such session after such date or if the legislature of the State is not in session on such date, [twenty-four months] *forty-two months* after the beginning of the first regular session of the legislature beginning after such date,

whichever occurs later, the Secretary shall take the action prescribed by paragraph (2).

[(2) If upon the expiration of the period applicable under paragraph (1) an agreement is not in effect for the designation of a State Agency for a State, the Secretary shall until such an agreement is in effect take the following action:

[(A) During the first twelve months after the date of the expiration of the applicable period, the Secretary shall reduce by 25 percent the amount of each allotment, grant, loan, and loan guarantee made to and each contract entered into with an individual or entity in such State during such period under this Act or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.

[(B) During the second twelve months after such expiration date, the Secretary shall reduce by 50 percent the amount of each such allotment, grant, loan, loan guarantee, and contract.

[(C) During the third twelve months after such expiration date, the Secretary shall reduce by 75 percent the amount of each such allotment, grant, loan, loan guarantee, and contract.

[(D) After the expiration of thirty-six months after such expiration date, the Secretary may not make or enter into any such allotment, grant, loan, loan guarantee, or contract.]

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TITLE XVII—HEALTH INFORMATION AND HEALTH PROMOTION

GENERAL AUTHORITY

SEC. 1701. (a) The Secretary shall—

(1) formulate national goals, and a strategy to achieve such goals, with respect to health information and health promotion, preventive health services, and education in the appropriate use of health care;

(2) analyze the necessary and available resources for implementing the goals and strategy formulated pursuant to paragraph (1), and recommend appropriate educational and quality assurance policies for the needed manpower resources identified by such analysis;

(3) undertake and support necessary activities and programs to—

(A) incorporate appropriate health education components into our society, especially into all aspects of education and health care,

(B) increase the application and use of health knowledge, skills, and practices by the general population in its patterns of daily living, and

(C) establish systematic processes for the exploration, development, demonstration, and evaluation of innovative health promotion concepts;

(4) undertake and support research and demonstrations respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(5) undertake and support appropriate training in the operation of programs concerned with, health information and health promotion, preventive health services, and education in the appropriate use of health care;

(6) undertake and support, through improved planning and implementation of tested models and evaluation of results, effective and efficient programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(7) foster the exchange of information respecting, and foster cooperation in the conduct of, research, demonstration, and train-

ing programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(8) provide technical assistance in the programs referred to in paragraph (7); [and]

(9) use such other authorities for programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care as are available and coordinate such use with programs conducted under this title[.]; *and*

(10) establish within the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion, which shall—

(A) coordinate all activities within the Department which relate to health information and health promotion, preventive health services, and education in the appropriate use of health care;

(B) coordinate its activities with similar activities or organizations in the private sector;

(C) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters;

(D) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine; and

(E) have a Director appointed by the Secretary.

[The Secretary shall administer this title in a manner consistent with the national health priorities set forth in section 1502 and with health planning and resourced development activities undertaken under titles XV and XVI.]

The Secretary shall administer this title in cooperation with health care providers, educators, voluntary organizations, and businesses in order to encourage the dissemination of health information and health promotion activities.

(b) For payments under grants and contracts under this title (other than grants and contracts under sections 1707, 1708, and 1709) there are authorized to be appropriated $7,000.000 for the fiscal year ending September 30, 1977, $10,000,000 for the fiscal year ending September 30, 1978, $14,000,000 for the fiscal year ending September 30, 1979, $14,000,000 for the fiscal year ending September 30, 1980, $15,000,000 for the fiscal year ending September 30, 1981, [and] $16,000,000 for the fiscal year ending September 30, 1982, *$2,300,000 for the fiscal year ending September 30, 1983, $2,426,500 for the fiscal year ending September 30, 1984, and $2,547,825 for the fiscal year ending September 30, 1985.*

(c) No grant may be made or contract entered into under this title unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in

such form and manner and contain such information as the Secretary may prescribe. Contracts may be entered into under this title without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

* * * * * * *

COMMUNITY PROGRAMS

SEC. 1703. (a) The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) new and innovative programs in health information and health promotion, preventive health services, and education in the appropriate use of health care, and may specifically—

(1) support demonstration and training programs in such matters which programs (A) are in hospitals, ambulatory care settings, home care settings, schools, day care programs for children, and other appropriate settings representative of broad cross sections of the population, and include public education activities of voluntary health agencies, professional medical societies, and other private nonprofit health organizations, (B) focus on objectives that are measurable, and (C) emphasize the prevention or moderation of illness or accidents that appear controllable through individual knowledge and behavior;

(2) provide consultation and technical assistance to organizations that request help in planning, operating, or evaluating programs in such matters;

(3) develop health information and health promotion materials and teaching programs including (A) model curriculums for the training of educational and health professionals and paraprofessionals in health education by medical, dental, and nursing schools, schools of public health, and other institutions engaged in training of educational or health professionals, (B) model curriculums to be used in elementary and secondary schools and institutions of higher learning, (C) materials and programs for the continuing education of health professionals and paraprofessionals in the health education of their patients, (D) materials for public service use by the printed and broadcast media, and (E) materials and programs to assist providers of health care in providing health education to their patients; and

(4) support demonstration and evaluation programs for individual and group self-help programs designed to assist the participant in using his individual capacities to deal with health problems, including programs concerned with obesity, hypertension, and diabetes.

(b) The Secretary is authorized to make grants to States and other public and nonprofit entities to assist them in meeting the costs of demonstrating and evaluating programs which provide information respecting the costs and quality of health care or information respecting health insurance policies and prepaid health plans, or information respecting both. [After the development of models pursuant to sections 1704(4) and 1704(5) for such informa-

tion, no grant may be made under this subsection for a program unless the information to be provided under the program is provided in accordance with one of such models applicable to the information.]

(c) The Secretary is authorized to support by grant or contract (and to encourage others to support) private nonprofit entities working in health information and health promotion, preventive health services, and education in the appropriate use of health care. The amount of any grant or contract for a fiscal year beginning after September 30, 1978, for an entity may not exceed 25 per centum of the expenses of entity for such fiscal year for health information and health promotion, preventive health services, and education in the appropriate use of health care.

INFORMATION PROGRAMS

SEC. 1704. The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health service, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. Such activities may include at least the following:

(1) The publication of information, pamphlets, and other reports which are specially suited to interest and instruct the health consumer, which information, pamphlets, and other reports shall be updated annually, shall pertain to the individual's ability to improve and safeguard his own health; shall include material, accompanied by suitable illustrations, on child care family life and human development, disease prevention (particularly prevention of pulmonary disease, cardiovascular disease, and cancer) physical fitness, dental health, environmental health, nutrition, safety and accident prevention, drug abuse and alcoholism, mental health, management of chronic diseases (including diabetes and arthritis), and venereal diseases; and shall be designed to reach populations of different languages and of different social and economic backgrounds.

(1) Securing the cooperation of the communication media, providers of health care, schools, and others in activities designed to promote and encourage the use of health maintaining information and behavior.

(3) The study of health information and promotion in advertising and the making to concerned Federal agencies and others such recommendations respecting such advertising as are appropriate.

(4) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others (except individual health practitioners) of information for use by the public respecting the cost and quality of health care, including information to enable the public to make comparisons of the cost and quality of health care.

[(5) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others

of information for use by the public respecting health insurance policies and prepaid health plans, including information on the benefits provided by the various types of such policies and plans, the premium charges for such policies and plans, exclusions from coverage or eligibility for coverage, cost sharing requirements, and the ratio of the amounts paid as benefits to the amounts received as premiums and information to enable the public to make relevant comparisons of the costs and benefits of such policies and plans.

[(6) Assess, with respect to the effectiveness, safety, cost, and required training for and conditions of use, of new aspects of health care and new activities, programs, and services designed to improve human health and publish in readily understandable language for public and professional use such assessments and, in the case of controversial aspects of health care, activities, programs, or services, publish differing views or opinions respecting the effectiveness, safety, cost, and required training for and conditions of use, of such aspects of health care, activities, programs, or services.]

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[OFFICE OF HEALTH INFORMATION, HEALTH PROMOTION AND PHYSICAL FITNESS AND SPORTS MEDICINE

[SEC. 1706. (a) The Secretary shall establish within the Office of the Assistant Secretary for Health an Office of Health Information, Health Promotion and Physical Fitness and Sports Medicine which shall—

[(1) coordinate all activities within the Department which relate to health information and health promotion, preventive health services, and education in the appropriate use of health care;

[(2) coordinate its activities with similar activities of organizations in the private sector;

[(3) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters; and

[(4) support projects, conduct research, and disseminate information in the areas of physical fitness and sports medicine.

[(b) The Office shall also—

[(1) assist, and foster research, investigations, and model projects on the nature of physical fitness, the development of physical fitness, and the relation of physical fitness to health;

[(2) assist, and foster research and investigations into the utilization of sports medicine, the development of sports medicine techniques, and the application of sports medicine throughout organized systems of athletic competition and in personal physical fitness development activities at every age and competition level;

[(3) foster and assist research into the proper role of nutrition in physical fitness programs;

[(4) promote the coordination of research and model programs conducted by the Office with similar programs conducted by other agencies of the Federal Government and other public and private organizations;

[(5) communicate the results of the studies in the widest possible manner to the American people and to special groups with particular interests and special needs in the development of physical fitness, such as young children, the handicapped, senior citizens, and workers in occupations which present special risks of physical disability; and

[(6) have a Director appointed by the Secretary.

[(c) The President's Council on Physical Fitness shall serve as the Advisory Body of the Office on all matters related to physical fitness. The activities of the Office and guidelines for the physical fitness programs supported by the Office shall be in conformance to guidelines developed by the President's Council on Physical Fitness.]

[PROJECT GRANTS TO STATE COUNCILS ON PHYSICAL FITNESS FOR PHYSICAL FITNESS IMPROVEMENTS

[SEC. 1707. (a) The Office may make grants to each State for the establishment by the Governor of a State Council on Physical Fitness or appropriate similar administrative unit.

[(b) The State Council shall consist of at least fifteen members, chosen by the Governor to serve terms of four years, and appointed from among persons who have distinguished records in the areas of physical fitness, sports medicine, public health, athletic competition, education, labor, business management, and nutrition.

[(c) It shall be the duty of the State Council on Physical Fitness to—

[(1) promote the development of physical fitness with the assistance of local health and educational agencies, business, labor unions, health action and advocacy groups, religious, fraternal and social organizations, community based multiservice recreational agencies, and health maintenance organizations;

[(2) assess the physical fitness and nutrition status of residents of the State;

[(3) plan and administer a program of grants-in-aid to support physical fitness projects, research projects, and public information efforts to promote the development of physical fitness for the residents of the State;

[(4) evaluate and improve the availability and quality of sports medicine and athletic trainer programs in the State.

[(d) Each State shall be eligible for a grant under this section in an amount which is equal to not less than 1 per centum of the funds appropriated for the purposes of this section. The first $75,000 of grant funds to each State under this section shall not be made until an amount equal to the amount of the grant is made available to the State for the purposes of this section from non-Federal sources.

[(e) Funds made available for the purposes of this section shall not be used to supplant non-Federal funds.

[(f) Fifty per centum of the funds appropriated under section 1708(c) shall be allocated for the purposes of this section.

[(g) In submitting an annual application for funds under this section the applicant must provide a description of all projects intended to be funded under subsection (c)(3).]

[PROJECT GRANTS FOR PHYSICAL FITNESS IMPROVEMENT AND RESEARCH PROJECTS

[Sec. 1708. (a) The Director of the Office may make grants or enter into contracts with public or private entities to conduct research and establish model projects with regard to improvement of physical fitness.

[(b) Projects encompassed under this section may encompass—

[(1) entire small communities, both urban and rural,

[(2) educational settings for a variety of age groups,

[(3) occupational settings,

[(4) groups of handicapped individuals, and

[(5) groups of senior citizens.

[(c) There are authorized to be appropriated for the purposes of section 1707, section 1706, and this section $6,000,000 for the fiscal year ending September 30, 1980, and $6,000,000 for the fiscal year ending September 30, 1981.]

[NATIONAL PROGRAM ON SPORTS MEDICINE RESEARCH

[Sec. 1709. (a) The Office shall establish a program of project grants to conduct research into the problem of athletic injuries with specific concentration on frequency of injuries, seriousness of injuries, the development of training and conditioning techniques and the development of athletic protective equipment to enable participants to avoid injuries to the maximum extent feasible, recovery rates, and problems associated with full recovery from athletic injuries.

[(b) The Office shall, in cooperation with the President's Council on Physical Fitness, establish a Clearinghouse on Sports Medicine Research to disseminate the results of that research to practitioners in relevant fields of health care and physical fitness.

[(c) There are authorized to be appropriated to carry out the purposes of this section $1,500,000 for the fiscal year ending September 30, 1980, and $1,500,000 for the fiscal year ending September 30, 1981.]

[CONFERENCE ON EDUCATION IN LIFETIME SPORTS

[Sec. 1710. (a) The Office and the Office of Education of the Department of Health, Education, and Welfare shall conduct a joint conference during 1979 on the teaching and support of educational programs in lifetime sports by secondary and postsecondary educational institutions.

[(b) The purpose of the Conference shall be to explore current programs on lifetime sports within these institutions and to support the expansion of such educational programs in other institutions of secondary and postsecondary education.]

TITLE XVIII—PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

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AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF COMMISSION

SEC. 1804. (a) AUTHORIZATIONS.—To carry out this title there are authorized to be appropriated $5,000,000 for the fiscal year ending September 30, 1979, $5,000,000 for the fiscal year ending September 30, 1980, $5,000,000 for the fiscal year ending September 30, 1981, [and] $5,000,000 for the fiscal year ending September 30, 1982, *$1,100,000 for the fiscal year ending September 30, 1983, and $1,100,000 for the fiscal year ending September 30, 1984.*

(b) FEDERAL ADVISORY COMMITTEE ACT; TERMINATION.—The Commission shall be subject to the Federal Advisory Committee Act, except that, under section 14(a)(1)(B) of such Act, the Commission shall terminate on [December 31, 1982.] *December 31, 1984.*

TITLE XIX—BLOCK GRANTS

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PART B—ALCOHOL AND DRUG ABUSE AND MENTAL HEALTH SERVICES BLOCK GRANT

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GRANTS AND ALLOTMENTS

SEC. 1912. (a)(1) The Secretary may use not more than 1 percent of the amount appropriated under section 1911 for any fiscal year to make grants to public and nonprofit private entities for projects for the training and retraining of employees adversely affected by changes in the delivery of mental health services and for providing such employees assistance in securing employment.

(2) No grant may be made by the Secretary under paragraph (1) unless an application therefor has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such manner, and contain and be accompanied by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under paragraph (1).

[(b)(1) From the remainder of the amount appropriated under section 1911 for any fiscal year, the Secretary shall allot to each State an amount which bears the same ratio to such remainder for that fiscal year as the amounts—

[(A) which would have been provided by the Secretary to the State and entities in the State under the Community Mental

Health Centers Act and the Mental Health Systems Act for fiscal year 1981 if the Secretary had obligated all the funds for mental health services available for such Acts under Public Law 96–536, and

[(B) provided by the Secretary to the State and entities in the State under the laws referred to in subparagraphs (C) and (D) of paragraph (2) for fiscal year 1980,

bore to the total amount appropriated for mental health services for fiscal year 1981 under Public Law 96–536 under the Community Mental Health Centers Act and the Mental Health Systems Act and the total amount appropriated for fiscal year 1980 for the provisions of law referred to in subparagraphs (C) and (D) of paragraph (2).

[(2) The provisions of law referred to in paragraph (1) are the following provisions of law as in effect on the day before the date of the enactment of the Omnibus Budget Reconciliation Act of 1981:

[(A) The Community Mental Health Centers Act.

[(B) The Mental Health Systems Act.

[(C) Sections 301 and 312 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.

[(D) Sections 409 and 410 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act.

[(3) To the extent that all the funds appropriated under section 1911 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

[(A) one or more States have not submitted an application or description of activities in accordance with section 1915 for the fiscal year;

[(B) one or more States have notified the Secretary that they do not intent to use the full amount of their allotment; or

[(C) some State allotments are offset or repaid under section 1916(b)(3);

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year without regard to this paragraph.]

(b)(1) From the remainder of the amount appropriated under section 1911 for any fiscal year, the Secretary shall allot to each State an amount which bears the same ratio to such remainder for that fiscal year as the amounts—

(A) which would have been provided by the Secretary to the State and entities in the State under section 301 of this Act for State mental health services demonstrations and under the Community Mental Health Centers Act and the Mental Health Systems Act for mental health services for fiscal year 1981 if the Secretary had obligated all the funds for such purposes available for such Acts under Public Law 95–536, and

(B) provided by the Secretary to the State and entities in the State under the laws referred to in subparagraphs (D) and (E) of paragraph (2) for fiscal year 1980,

bore to the total amount appropriated for State mental health services demonstrations and mental health services for fiscal year 1981 under Public Law 96–536 for section 301 of this Act, the Community Mental

Health Centers Act and the Mental Health Systems Act and the total amount appropriated for fiscal year 1980 for the provisions of law referred to in subparagraphs (D) and (E) of paragraph (2).

(2) The provisions of law referred to in paragraph (1) are the following provisions of law as in effect on the day before the enactment of the Omnibus Budget Reconciliation Act of 1981:

(A) The Community Mental Health Centers Act.

(B) The Mental Health Systems Act.

(C) Section 301 of this Act.

(D) Sections 301 and 312 of the Comprehensive Alcohol Abuse and Alcoholism, Prevention, Treatment, and Rehabilitation Act of 1970.

(E) Sections 409 and 410 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act.

(3) For purposes of paragraph (1), the total amount appropriated under Public Law 96-536 for State mental health services demonstrations under section 301 of this Act shall be deemed not to exceed $20,000,000; and if such total amount did exceed $20,000,000, the amount that would have been provided to each State and entities in each State shall be ratably reduced for purposes of paragraph (1) (A) to conform to the limit prescribed by this paragraph.

(c) (1) If the Secretary—

(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this part be provided directly by the Secretary to such tribe or organization, and

(B) determines that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this part,

the Secretary shall reserve from amounts which would otherwise be allotted to such State under subsection (b) for the fiscal year the amount determined under paragraph (2).

(2) The Secretary shall reserve for the purpose of paragraph (1) from amounts that would otherwise be allotted to such State under subsection (b) an amount equal to the amount which bears the same ratio to the State's allotment for the fiscal year involved as the total amount provided or allotted for fiscal year 1980 by the Secretary to such tribe or tribal organization under the provisions of law referred to in subsection (b) (2) bore to the total amount provided or allotted for such fiscal year by the Secretary to the State and entities (including Indian tribes and tribal organizations) in the State under such provisions of law.

(3) The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

(4) In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this subsection, it shall submit to the Secretary a plan for such fiscal year which meets such criteria as the Secretary may prescribe.

(5) The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

(d) The Secretary shall conduct a study for the purpose of devising a formula for the equitable distribution of funds available for allotment to the States under subsection (b). In conducting the study, the Secretary shall take into account—

(1) the financial resources of the various States,

(2) the populations of the States, and

(3) any other factor which the Secretary may consider appropriate.

Before June 30, 1982, the Secretary shall submit a report to the Congress respecting the development of a formula and make such recommendations as the Secretary may deem appropriate in order to insure the most equitable distribution of funds under allotments under subsection (b).

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HEALTH PLANNING AND RESOURCES DEVELOPMENT AMENDMENTS OF 1979

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TITLE I—REVISION OF HEALTH PLANNING AUTHORITY

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EFFECTIVE DATE

SEC. 129. (a) The amendments made by this title (other than by sections 101, 102, 103(a), 103(b), 103(c), 104(c), 105, 106, 107, 110(c), 110(d), 110(e), 110(f), 111, 115(f), 116(d), 116(e), 117, 120, 123, 126, 127, and 128) shall take effect one year after the date of the enactment of this Act except that on and after the date of the enactment of this Act—

(1) the changes in the membership of the health systems agencies and the Statewide Health Coordinating Councils required by amendments to sections 1512, 1524, and 1531 shall be implemented through selections of members to fill vacancies occurring after such date,

(2) a health systems agency, a State health planning and development agency, and a Statewide Health Coordinating Council may make the organizational and related changes required by the amendments to sections 1512, 1522, 1523, 1524, and 1531 of the Public Health Service Act, and

(3) health systems agencies, State health planning and development agencies, and Statewide Health Coordinating Councils may act in accordance with the changes in their functions made by the amendments to sections 1513, 1522, 1523, 1524, and 1532 of the Public Health Service Act.

(b)(1) Except as provided in section 1516(c)(1)(C)(i) of the Public Health Service Act as amended by section 106, the amendments made by section 106 shall apply with respect to grants made under section 1516 of the Public Health Service Act after the date of the enactment of this Act from appropriations under an appropriation Act enacted for the fiscal year ending September 30, 1980.

[(2) The amendments made by sections 116(d), 116(e), 117, and 126 shall take effect on the date of the enactment of this Act, except that if the Secretary of Health, Education, and Welfare determines that any amendment made by any such section will require a State to change its laws before the State health planning and development agency designated for such State may perform its functions under section 1523(a)(4)(B) of the Public Health Service Act, such amendment shall take effect in such State—

[(A) if the legislature of the State is in a regular session on the date of the enactment of the Health Planning and Resources Development Amendments of 1979 and the legislature will be in session for at least twelve months from such date, twelve months from such date, or

[(B) if the legislature of the State is in session on such date of enactment but twelve months do not remain in such session after such date or if the legislature of the State is not in session on such date, twelve months after the beginning of the first regular session of the legislature beginning after such date.]

(2) The amendments made by sections 116(d), 116(e), 117, and 126 shall take effect on the date of the enactment of this Act, except that if the Secretary of Health and Human Services determines that any amendment made by any such section will require a State to change its laws before the State health planning and development agency designated for such State may perform its functions under section 1523(a)(4)(B) of the Public Health Service Act, such amendment shall take effect in such State—

(A) if the legislature of the State is in a regular session on the date of the enactment of the Health Programs Extension Act of 1980 and the legislature will be in session for at least twelve months from such date, forty-two months from such date, or

(B) if the legislature of the State is in session on such date of enactment but twelve months do not remain in such session after such date or if the legislature of the State is not in session on such date, forty-two months after the beginning of the first regular session of the legislature beginning after such date.

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The following citation refers to the Omnibus Budget Reconciliation Act of 1981.

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TITLE VI—HUMAN SERVICES PROGRAMS

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Subtitle B—Community Services Block Grant Program

SHORT TITLE

SEC. 671. This subtitle may be cited as the "Community Services Block Grant Act".

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APPLICATIONS AND REQUIREMENTS

SEC. 675. (a) Each State desiring to receive an allotment for a fiscal year under this subtitle shall submit an application to the Secretary. Each such application shall be in such form as the Secretary shall require. Each such application shall contain assurances by the chief executive officer of the State that the State will comply with subsection (b) and will meet the conditions enumerated in subsection (c).

(b) After the expiration of the first fiscal year in which a State received funds under this subtitle, no funds shall be allotted to such State for any fiscal year under this subtitle unless the legislature of the State conducts public hearings on the proposed use and distribution of funds to be provided under this subtitle for such fiscal year.

(c) As part of the annual application required by subsection (a), the chief executive officer of each State shall certify that the State agrees to—

(1) use the funds available under this subtitle—

(A) to provide a range of services and activities having a measurable and potentially major impact on the causes of poverty in the community or those areas of the community where poverty is a particularly acute problem;

(B) to provide activities designed to assist low-income participants including the elderly poor—

(i) to secure and retain meaningful employment;

(ii) to attain an adequate education;

(iii) to make better use of available income;

(iv) to obtain and maintain adequate housing and a suitable living environment;

(v) to obtain emergency assistance through loans or grants to meet immediate and urgent individual and family needs, including the need for health services, nutritious food, housing, and employment-related assistance;

(vi) to remove obstacles and solve problems which block the achievement of self-sufficiency;

(vii) to achieve greater participation in the affairs of the community; and

(viii) to make more effective use of other programs related to the purposes of this subtitle;

(C) to provide on an emergency basis for the provision of such supplies and services, nutritious foodstuffs, and related services, as may be necessary to counteract conditions of starvation and malnutrition among the poor;

(D) to coordinate and establish linkages between governmental and other social services programs to assure the effective delivery of such services to low-income individuals; and

(E) to encourage the use of entities in the private sector of the community in efforts to ameliorate poverty in the community;

(2)(A)(i) use [for fiscal year 1982 only] *for fiscal year 1982 and the first two quarters of fiscal year 1983*, not less than 90 percent of the funds allotted to the State under section 674 to make

grants to use for the purposes described in clause (1) to eligible entities (as defined in section 673(1)) or to organizations serving seasonal or migrant farmworkers; and

(ii) use, for [fiscal year 1983] *the third and fourth quarters of fiscal year 1983* and for each subsequent fiscal year, not less than 90 percent of the funds allotted to the State under section 674 to make grants to political subdivisions of the State for the political subdivisions to use for the purposes described in clause (1) directly or to nonprofit private community organizations which have a board which meets the requirements of clause (3), or to migrant and seasonal farm worker organizations; and

(B) provide assurances that the State will not expend more than 5 percent of its allotment under section 674 for administrative expenses at the State level;

(3) provide assurances that, in the case of a community action agency or nonprofit private organization, each board will be constituted so as to assure that (A) one-third of the members of the board are elected public officials, currently holding office, or their representatives, except that if the number of elected officials reasonably available and willing to serve is less than one-third of the membership of the board, membership on the board of appointive public officials may be counted in meeting such one-third requirement; (B) at least one-third of the members are persons chosen in accordance with democratic selection procedures adequate to assure that they are representative of the poor in the area served; and (C) the remainder of the members are officials or members of business, industry, labor, religious, welfare, education, or other major groups and interests in the community;

(4) give special consideration in the designation of local community action agencies under this subtitle to any community action agency which is receiving funds under any Federal antipoverty program on the date of the enactment of this Act, except that (A) the State shall, before giving such special consideration, determine that the agency involved meets program and fiscal requirements established by the State; and (B) if there is no such agency because of any change in the assistance furnished to programs for economically disadvantaged persons, the State shall give special consideration in the designation of community action agencies to any successor agency which is operated in substantially the same manner as the predecessor agency which did receive funds in the fiscal year preceding the fiscal year for which the determination is made;

(5) provide assurances that the State may transfer funds, but not to exceed 5 percent of its allotment under section 674, for the provisions set forth in this subtitle to services under the Older Americans Act of 1965, the Head Start program under subchapter B of chapter 8 of subtitle A of this title, or the energy crisis intervention program under title XXVI of this Act (relating to low-income home energy assistance);

(6) prohibit any political activities in accordance with subsection (e);

(7) prohibit any activities to provide voters and prospective voters with transportation to the polls or provide similar assist-

ance in connection with an election or any voter registration activity;

(8) provide for coordination between antipoverty programs in each community, where appropriate, with emergency energy crisis intervention programs under title XXVI of this Act (relating to low-income home energy assistance) conducted in such community;

(9) provide that fiscal control and fund accounting procedures will be established as may be necessary to assure the proper disbursal of and accounting for Federal funds paid to the State under this subtitle, including procedures for monitoring the assistance provided under this subtitle, and provide that at least every year each State shall prepare, in accordance with subsection (f), an audit of its expenditures of amounts received under this subtitle and amounts transferred to carry out the purposes of this subtitle; and

(10) permit and cooperate with Federal investigations undertaken in accordance with section 679.

The Secretary may not prescribe the manner in which the States will comply with the provisions of this subsection.

(d)(1) In addition to the requirements of subsection (c), the chief executive officer of each State shall prepare and furnish to the Secretary a plan which contains provisions describing how the State will carry out the assurances contained in subsection (c). The chief executive officer of each State may revise any plan prepared under this paragraph and shall furnish the revised plan to the Secretary.

(2) Each plan prepared under paragraph (1) shall be made available for public inspection within the State in such a manner as will facilitate review of, and comment on, the plan.

(e) For purposes of chapter 15 of title 5, United States Code, any nonprofit private organization receiving assistance under this subtitle which has responsibility for planning, developing, and coordinating community antipoverty programs shall be deemed to be a State or local agency. For purposes of clauses (1) and (2) of section 1502(a) of such title, any such organization receiving assistance under this subtitle shall be deemed to be a State or local agency.

(f) Each audit required by subsection (c)(9) shall be conducted by any entity independent of any agency administering activities or services carried out under this subtitle and shall be conducted in accordance with generally accepted accounting principles. Within 30 days after the completion of each audit, the chief executive officer of the State shall submit a copy of such audit to the legislature of the State and to the Secretary.

(g) The State shall repay to the United States amounts found not to have been expended in accordance with this subtitle or the Secretary may offset such amounts against any other amount to which the State is or may become entitled under this subtitle.

(h) The Comptroller General of the United States shall, from time to time, evaluate the expenditures by States of grants under this subtitle in order to assure that expenditures are consistent with the provisions of this subtitle and to determine the effectiveness of the State in accomplishing the purposes of this subtitle.

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ADDITIONAL VIEWS OF SENATOR JEREMIAH DENTON, FOR INCLUSION IN THE REPORT TO ACCOMPANY S. 2311

Although I strongly support the vast majority of the provisions of S. 2311, and voted to report the bill favorably, I must raise objection to the Eagleton-Quayle amendment concerning the Community Services Block Grant (CSBG). As Chairman of the Aging, Family and Human Services Subcommittee, which has jurisdiction over the block grant, I must oppose this amendment because it violates the trust Congress placed in the States as part of the Omnibus Budget Reconciliation Act of 1981, because it is costly, and because it is unnecessary.

The amendment extends for an additional six months the Federal requirement in Public Law 97–35 that 90 percent of CSBG money given to a State in fiscal year 1982 be passed through the local Community Action Programs (CAPs) responsible for actually providing the services. Public Law 97–35 also allowed States the option, in fiscal year 1982 only, of administering the block grant themselves or having the Department of Health and Human Services administer it for them. Under current law, at the end of fiscal year 1982 all States would assume responsibility for the block grant and the 90 percent pass-through provision would be dropped.

The argument advanced in support of the amendment is that States that have not directly administered the program need a 6-month familiarization period to guarantee a smooth transition from Federal to State administration. This rationale is faulty in several respects.

To change policy at this late date would constitute a breach of faith with the States. The States now administering the program and those that will assume administration at the end of the current fiscal year have undertaken extensive planning efforts to distribute fiscal year 1983 CSBG funds. This planning was undertaken in the belief that the States would have total discretion in the distribution of CSBG money. The 10 States not now administering the program have had an entire year to prepare for the transfer from Federal to State responsibility, and none of these States had indicated that an additional six months is necessary to prepare them for taking control of the CSBG. The extension of the 90 percent pass-through provision for six months will undermine State planning efforts and severely disrupt the smooth takeover of responsibilities by the States because States plan on a yearly basis, not for each six month period.

If this amendment is implemented, it will be costly because all the money spent on State planning efforts will have been completely wasted, and more money will have to be expended for new plans. Another consideration is the potential for auditing and compliance problems from this abrupt switch in policy. This, in turn, increases the possibility of costly and time-consuming litigation to force State compliance with the Federal statute.

Finaly, there is no evidence that this amendment is necessary. The amendment incorrectly implies that the 37 states (including the District of Columbia) that immediately assumed administration of the block grant experienced numerous problems in the transition from federal to state control. Although there were some problems reported by these states, they were the result of the elimination of the Community Services Administration and the transfer of the Administration's responsibilities to the newly-created Office of Community Services within the Department of Health and Human Services. Any new office within an agency undergoes a period when the staff has not been fully established. OCS experienced these common problems at the outset, but the Office has now been operating efficiently for almost a full year, and the initial transition problems have been resolved. It is interesting to note that the four states that assumed responsibility for the CSBG since the beginning of fiscal year 1982 have reported no difficulties in the transfer from federal to state administration.

Of the 10 remaining states, none has indicated any aversion to assuming control of the block grant. In fact, the Governor of the State of New York has written to assure Secretary Schweiker that the state will assume control of the block grant as soon as the state legislature acts on the CSBG. Other states have likewise indicated that they will take control when their legislatures address the CSBG question.

Furthermore, neither the Aging, Family and Human Services Subcommittee staff nor the Department of Health and Human Services has received word from any of these 10 states that they expect to encounter serious difficulties in the assumption of the block grant.

This amendment is not a protection for the states, as has been contended, but rather a protection for existing Community Action Programs, whose services can range in quality from excellent to mediocre. Nothing in current law prevents a state from continuing to fund a CAP, or a CAP from applying for a grant in the next fiscal year, but current law does remove the federal requirement that states funnel 90% of the CSBG money to the CAPs. If a program is of high quality, it will likely continue to receive funds. If it is a mediocre program, funding could be terminated. But the key point to be made is that current law will allow state officials, who have the benefit of close contact with the agencies in question, to make this determination rather than having it made in Washington, D.C. A further consideration is that institutions other than CAPs that may develop new and innovative approaches to providing essential services at a lower cost would be precluded from receiving funds because of the pass-through provision.

In short, my opposition to the amendment rests in the firm belief that the states are willing and able to assume complete administration of the Community Services Block Grant and have been proceeding on the assumption that cumbersome federal requirements would be removed. States who have already assumed control report few difficulties in the transition, and there is little reason to believe that the remaining states will encounter unexpected problems. States deserve the chance to show what they can do if they are allowed to make specific funding decisions and to tailor programs to fit their individual needs. This amendment is a retreat from the progress this Congress has made toward a long overdue reordering of federal and state responsibilities, and I urge my colleagues to oppose this provision of S. 2311 when it reaches the Senate floor.

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